

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**UNITED STATES, *ex rel.*,
DILBAGH SINGH M.D.,
PAUL KIRSCH, M.D.,
V. RAO NADELLA, M.D., and
MARTIN JACOBS, M.D.,**

Plaintiffs,

v.

**BRADFORD REGIONAL MEDICAL
CENTER, V & S MEDICAL
ASSOCIATES, LLC,
PETER VACCARO, M.D.,
KAMRAN SALEH, M.D., and
DOES I through XX,**

Defendants.

Civil No. 04-186 Erie

Opinion

Dilbagh Singh M.D., Paul Kirsch, M.D., V. Rao Nadella, M.D., and Martin Jacobs, M.D., commenced this *qui tam* action pursuant to the federal False Claims Act (“FCA”), 31 U.S.C. §§ 3729, *et seq.*, against Bradford Regional Medical Center (“BRMC”), V&S Medical Associates, LLC (“V&S”), Peter Vaccaro, M.D., and Kamran Saleh, M.D. The Relators, Drs. Singh, Kirsch, Nadella, and Jacobs, allege that Defendants submitted, or caused to be submitted, false claims for payment to the Medicare program arising out of referrals from Drs. Vaccaro and Saleh to BRMC in violation of the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback Act, 42 U.S.C. § 1320a-7b.

I. Factual Background

Defendant BRMC is a Pennsylvania non-profit corporation. BRMC owns and operates a hospital in Bradford, Pennsylvania, providing inpatient and outpatient hospital services to the residents of McKean County and surrounding areas.

Defendants Drs. Saleh and Vaccaro specialize in the practice of internal medicine in Bradford, Pennsylvania. Prior to April 2000, Drs. Vaccaro and Saleh were employed by BRMC. In April 2000, they purchased their practice from BRMC and formed V&S Medical Associates, LLC (“V&S”). Defendant V&S is a limited liability company, the members of which are Drs. Saleh and Vaccaro. Drs. Saleh and Vaccaro are sole and equal owners of V&S. Drs. Saleh and Vaccaro are currently members of the medical staff of BRMC.

Relators are Dilbaugh Singh, M.D., Paul Kirsch, M.D., V. Rao Nadella, M.D., and Martin Jacobs, M.D. Relators are all physicians who practice in Bradford, Pennsylvania, and are or were members of the medical staff of BRMC. The Relators provide the same or similar services to patients as Drs. Saleh and Vaccaro.

Prior to 2001, Drs. Vaccaro and Saleh were a significant source of referrals to BRMC, both for inpatient admissions and for outpatient procedures, including diagnostic tests performed on a nuclear imaging camera located at BRMC. (Leonhardt Dep. at 18; BRMC 30(b)(6) Dep. at 97, 129, 175; Saleh Dep. at 17-22; Vaccaro Dep. at 18-20, 24.) In 2001, V&S began to consider obtaining a nuclear camera and installing it in its office, thus allowing V&S to perform nuclear imaging tests in-house, rather than referring such tests to BRMC.

In March 2001, upon learning of V&S’s plans to acquire their own nuclear camera, BRMC’s CEO, George Leonhardt, asked BRMC’s senior vice-president of operations, Glen Washington,

for information about Vaccaro and Saleh's nuclear medicine referrals, in order to determine "what kind of impact could that have on us." (Leonhardt Dep. at 94-95.)

Mr. Washington informed Mr. Leonhardt that annual gross nuclear medicine revenues were approximately \$2,798,578.00, of which approximately \$2,274,094.00 were outpatient revenues. (Email from Washington to Leonhardt, March 14, 2001 10:03 a.m.) Mr. Washington told Mr. Leonhardt that Drs. Vaccaro, Saleh, and Jamil (a physician who rented space in V&S's office) ordered 42.5% of the hospital's nuclear studies, and that V&S had enough nuclear medicine patients to support their own machine. (Email from Washington to Leonhardt, March 14, 2001 10:24 a.m., Saleh Dep., at 7-8).

Because Drs. Vaccaro and Saleh were a major referral source to the hospital, Mr. Leonhardt became concerned that their acquisition of a nuclear camera would have a "very detrimental impact on [BRMC's] attempt to establish a cardiology service." (BRMC 30(b)(6) Dep. at 94; see also, BRMC 30(b)(6) Dep. at 97; Leonhardt Dep., at 5-6.). From BRMC's perspective if key cardiology diagnostic services were offered in the offices of internal medicine physicians such services would not be available to support the work that the cardiologist would do at the hospital. (BRMC 30(b)(6) Dep. at 105.)

On April 3, 2001, Mr. Leonhardt met with Drs. Vaccaro and Saleh and explained that their acquisition of a nuclear camera would negatively impact the hospital's financial position and affect the recruitment of a cardiologist. (Saleh Dep., at 38-40; Letter from Leonhardt to Vaccaro and Saleh, July 30, 2001.)

Between April 3, 2001 and June 1, 2001, Mr. Leonhardt met with Drs. Vaccaro and Saleh on several more occasions. (Saleh Dep. at 61-62; Letter from Leonhardt to Vaccaro and Saleh, July 30, 2001.) In a subsequent letter, Mr. Leonhardt noted that the parties discussed the

possibility of entering into a joint venture “within the Safe Harbor exceptions to Stark II.” (Letter from Leonhardt to Vaccaro and Saleh, July 30, 2001; Saleh Dep. at 62.) However, despite these discussions, Drs. Vaccaro and Saleh decided to go ahead with their plans to acquire a nuclear imaging camera. (Saleh Dep. at 39-40.)

In May 2001, BRMC adopted a Policy on Physicians with Competing Financial Interests. The policy provided that, if a physician had a financial relationship with a competing health care entity that might have a significant impact upon the hospital, that physician would be ineligible for hospital privileges. (BRMC 30(b)(6) Dep. at 83, 86-87.) Specifically, the Policy states that “a practitioner who has a financial relationship with, or an ownership or investment interest in, any competing health care entity or services that has or may have a significant impact (as determined by the Board) upon the Medical Center: (i) shall be ineligible to be granted appointment (initial or reappointment) or clinical privileges to practice at the Medical Center and its facilities, and (ii) shall be ineligible for continued appointment and clinical privileges to practice at the Medical Center.” (Policy on Physicians with Competing Financial Interests, May 23, 2001, at 1.)

In June 2001, V&S entered into a 63-month lease with General Electric (“GE”) for a nuclear camera. (Saleh Dep. at 164-165.) Drs. Vaccaro and Saleh each executed personal guaranties in favor of GE. After the GE camera was placed in V&S’s office, the doctors’ changed their referral practices with respect to nuclear imaging. Rather than referring patients to BRMC for nuclear imaging tests as they had done previously, Drs. Vaccaro and Saleh began to perform such tests in their own office, thus decreasing their nuclear referrals to BRMC. (Saleh Dep. at 37; Vaccaro Dep. at 25; BRMC 30(b)(6) Dep. at 128; Leonhardt Dep. at 6-7.) However,

their referral practices with respect to inpatient admissions and other outpatient procedures did not change as a result of acquiring the nuclear camera. (Saleh Dep. at 37.)

BRMC was concerned that V&S might also reduce its other inpatient and outpatient referrals to the hospital. Among other things, although V&S did not currently offer CT scans or MRIs in their office, BRMC was concerned that they might begin to do so, thus reducing their referrals to the hospital for such procedures. (Leonhardt Dep. at 57-58; Report of Charles T. Day, undated, at 14.)

After adopting the Policy against competing interests, Mr. Leonhardt told Drs. Vaccaro and Saleh that they were subject to the policy and faced the possibility of losing their hospital privileges if they continued competing against the hospital. (Saleh Dep. at 43-45; Vaccaro Dep. at 42; Leonhardt Dep. at 19-20.) Drs. Saleh and Vaccaro were informed by BRMC that by operating a nuclear camera in their office, the doctors would likely be in violation of the new Policy.

In December 2001, the Board of BRMC appointed a fact-finding committee to determine if V&S was in violation of the Policy and requested information from Drs. Saleh and Vaccaro as part of this effort. (Letter from Leonhardt to Saleh, 1/2/2002; Letter from Leonhardt to Vaccaro, 1/28/2002.)

In January 2002, Drs. Saleh and Vaccaro, through their legal counsel Marc Raspanti, Esquire, objected to BRMC's Policy and its application to Drs. Saleh and Vaccaro. (Letter from Raspanti to Leonhardt, 1/22/2002; Letter from Kabala to Vaccaro, 12/4/2001.) In the letter Mr. Raspanti stated that the hospital's Policy and Procedures "violate federal law, in particular, the federal anti-kickback criminal statute." (Raspanti Letter, 1/22/2002, at 1 (citing Kabala Letter, 12/4/01).) Mr. Raspanti also noted that the Stark Statute and the False Claims Act provide civil

penalties “for those who enter into arrangements which compensate based upon referrals.” (Raspanti Letter, 1/22/2002, at 2.) Finally, Mr. Raspanti asserted that the “Medical Center is conditioning privileges on referrals streams. This is precisely the type of arrangement that the anti-kickback laws were intended to prevent.” (Id.)

On February 15, 2002, Mr. Raspanti sent another letter to Mr. Leonhardt, noting that “the anti-kickback laws are violated even where only ‘one purpose’ of a payment or exchange is to induce referrals.” (Letter from Raspanti to Leonhardt, 2/15/2002, at 1.) Mr. Raspanti also noted that, since July 2001, Drs. Vaccaro and Saleh had been subject to numerous case reviews, and that “[s]uch harassment of physicians who are perceived as having a financial conflict of interest is an absolute abuse of the peer review process.” (Id. at 5.) Mr. Raspanti stated: “We know of no case that more clearly establishes a hospital’s attempt to extract an exclusive referral stream from a physician.” (Id.)

In May 2002, the Board of BRMC made a preliminary determination that Drs. Saleh and Vaccaro had significant competing financial interests pursuant to the Policy, and so informed them of that fact. (BRMC 30(b)(6) Dep. at 128.) On June 11, 2002, Mr. Leonhardt sent a letter to Drs. Vaccaro and Saleh indicating that BRMC and V&S Medical Associates should discuss “[w]hether there is interest . . . in working together in regard to the equipment and services in question, be it through a joint venture or other appropriate means.” (Letter from Leonhardt to V&S, 6/11/2002.)

In a June 26, 2002 letter, Mr. Leonhardt proposed the possibility of BRMC entering into a relationship “whereby diagnostic services could be provided by the hospital ‘under arrangement’ with an entity owned by physicians.” (Letter from Leonhardt to V&S, 6/26/2002; BRMC 30(b)(6) Dep. at 134.) The proposed joint venture was offered to all physicians on the

BRMC medical staff and contemplated a physician-owned diagnostic center, formed by the staff physicians, to provide diagnostic tests. (Letter from Leonhardt to V&S, 7/30/2001; Leonhardt Letter, 6/26/2002; BRMC 30(b)(6) Dep. at 135.) This diagnostic center would enter into a contract with BRMC, whereby the center would be paid a fixed amount for each test furnished to hospital patients. (Leonhardt Letter, 6/26/2002.) The hospital, not the diagnostic center, would then bill the patient or third-party payors for the service. (Id.) This proposed “under arrangements” venture would not simply provide nuclear imaging tests, but would also provide other diagnostic procedures such as CTs and MRIs, which were not then being provided by V&S. (Leonhardt Dep. at 72, 73.) In his letters to Drs. Vaccaro and Saleh, Mr. Leonhardt stressed the need to structure the venture in such a way that it satisfied the Stark statute. (Leonhardt Letter, 6/26/2002; Leonhardt Letter, 7/30/2001.)

BRMC engaged Stroudwater Associates, a consulting firm, to perform an analysis of the proposed “Under Arrangements” Joint Venture. (BRMC 30(b)(6) Dep. at 135-136.) Between the months of December 2002 and March 2003, several meetings were held between representatives of BRMC and Drs. Saleh and Vaccaro, as well as their respective legal counsel, regarding the possibility of resolving their dispute concerning the Policy. (Leonhardt Dep. at 37-44.) During these meetings, a possible sublease arrangement was also discussed and considered as an option to resolve the dispute while the proposed Joint Venture was under consideration. (Id. at 43.)

In a January 17, 2003 letter to BRMC’s counsel, V&S’s attorney, Mr. Raspanti, stated as follows:

In [the January 10, 2003] letter, the Medical Center directly threatens to revoke the medical staff privileges of Drs. Saleh and Vaccaro based upon their refusal to be coerced into a poor medical, and even worse, business decision.

(Letter from Raspanti to Alan J. Steinberg, 1/17/2003, at 1.) Mr. Raspanti described BRMC's conduct with respect to the Policy as "shocking, disappointing and, quite frankly, economic blackmail." (Id. at 2.) Mr. Raspanti asked for "[a]ll opinions concerning the legality of the nuclear camera venture" contemplated between BRMC and physicians on the hospital medical staff. (Id. at 3.) He further stated: "I am sure that we can all agree that neither party wishes to become involved in a business venture which is in violation of federal or state law." (Id. at 3 n.4.)

In a February 5, 2003 letter, Edward Kabala, an attorney for V&S, stated as follows:

While the "under arrangements" [joint venture] process may be entirely legal, we would want to be sure that we will get an unconditional opinion or an advisory opinion from the Office of the Inspector General, to the effect that the final arrangement and the process that led to it would not be deemed inappropriate.

(Letter from Kabala to Steinberg, 2/5/2003, at 4.)

The parties considered it essential that they obtain an advisory opinion from the Office of the Inspector General regarding the legality of the venture before entering into any "under arrangements" joint venture. (Kabala letter, 2/5/2003, at 4; BRMC 30(b)(6) Dep. at 138; Saleh Dep. at 101.)

At some point in early 2003, the parties began discussing an alternative resolution, under which BRMC would agree to sublease the nuclear camera from V&S. (Letter from Steinberg to Jodeen Hobbs, 3/14/2003; Letter from Kabala to Steinberg, 2/11/2003; BRMC 30(b)(6) Dep. at 126-127, 139, 151; Leonhardt Dep. at 36-37.) In a February 11, 2003 letter, V&S's attorney Mr. Kabala stated that Vaccaro, Saleh, and V&S Medical Services "have indicated that all of their Nuclear Medicine Studies can be accommodated by a combination of their current camera and those at BRMC." (Kabala Letter, 2/11/2003, at 2.)

On April 16, 2003, the parties entered into an Agreement providing that the parties would enter into a sublease for the nuclear camera, while continuing efforts to develop an under arrangements venture. (Sublease Agreement, April 16, 2003.) Drs. Vaccaro and Saleh individually signed this Agreement, agreeing to be bound by its terms. (Id. at 4.)

The Sublease Agreement provided that BRMC would sublease the GE Equipment from V&S, and then use the GE Equipment to provide diagnostic tests for patients of BRMC. (Id. at §1.) V&S would, in turn, agree to a covenant not to compete with the provision of nuclear cardiology services by BRMC for the term of the Sublease Agreement. (Id. at §7(a).) Section 6 of the Sublease Agreement allowed BRMC to change or upgrade the equipment at its discretion, while section 5 required the parties to continue good faith efforts with respect to the development of the proposed “under arrangements” joint venture. (Id. at §6, §5.)

From April through September, 2003, BRMC and V&S negotiated the specific terms of an eventual final sublease agreement. During this time V&S provided BRMC with data regarding its performance of nuclear camera services in its office.

Before entering into a final sublease, BRMC had a “fair market value” assessment prepared by an accountant, Charles T. Day. (Leonhardt Dep. at 54; BRMC 30(b)(6) Dep. at 146-148.) BRMC sought this report to determine whether BRMC was paying fair market value under the proposed sublease arrangement. (Leonhardt Dep. at 54-55; BRMC 30(b)(6) Dep. at 148-149.) In September 2003, the Board of BRMC received Mr. Day’s report . The report concluded that the amounts to be paid pursuant to the proposed sublease were reasonable. (BRMC 30(b)(6) Dep. Appx., at 146-149.)

In performing his fair market value analysis, Mr. Day compared the revenues BRMC expected to generate with the sublease in place to the revenues BRMC expected to receive

without the sublease in place. (Report of Charles T. Day, C.P.A.; Leonhardt Dep. at 55-56.) The projections were based on the expectation that V&S would refer such business to the hospital if the sublease arrangement was approved. (Id.) According to Defendants, the basis of Mr. Day's report was what benefits BRMC would have lost had it terminated the medical staff appointment and clinical privileges of Drs. Vaccaro and Saleh pursuant to BRMC's Policy. BRMC advised Drs. Vaccaro and Saleh that its valuation expert indicated that he could support the fair market value of the Sublease, however neither Vaccaro nor Saleh received or reviewed a copy of Mr. Day's written valuation.

Mr. Leonhardt considered and relied on Mr. Day's report before executing the Equipment Sublease. (Leonhardt Dep. at 55-56.) Mr. Leonhardt had to obtain Board approval to enter into the sublease arrangement. (Leonhardt Dep. at 65-66.) He prepared a summary of the sublease arrangement to use in his presentation to the Board. (Id. at 67, 68.) This summary indicated that BRMC expected to generate \$402,000 in profit from the additional nuclear imaging referrals expected to be made by V&S following execution of the sublease. (Id. at 71-72; Summary, April 2003, attached as doc. 8 to Relators' Appx. (Doc. 117).) Mr. Leonhardt made a presentation to the Board and obtained formal approval for the sublease arrangement. (Leonhardt Dep. at 72-73.) The V&S Defendants did not see a copy of the internal summaries regarding the Sublease that were prepared for the BRMC Board of Directors.

Effective October 1, 2003, BRMC and V&S entered into an Equipment Sublease, which set forth in more detail the terms of the preliminary Sublease Agreement. (BRMC 30(b)(6) Dep. at 183-184; Equipment Sublease, Oct. 1, 2003.) The Equipment Sublease was for a five-year term expiring on September 30, 2008. The Equipment Sublease called for BRMC to pay V&S \$6,545 per month, representing the amounts due from V&S to GE for the GE nuclear camera

under V&S's lease with GE. (Equipment Sublease, at §2(d)(i)(1).) The Equipment Sublease also called for BRMC to pay V&S \$23,655 per month for all other rights under the Equipment Sublease, including the covenant not to compete. (Id. at §2(d)(i)(2).) The Equipment Sublease expressly provided that if the proposed "under arrangements" joint venture is successfully implemented then the Equipment Sublease would automatically terminate. (Id. at §2(c).)

Drs. Vaccaro and Saleh individually signed the Equipment Sublease, specifically agreeing to be bound by the terms and conditions of the covenant not to compete set forth in Section 14. (Id. at 17.) Section 14 of the Equipment Sublease provides that Drs. Vaccaro and Saleh will not own or operate competing nuclear cardiology imaging equipment within thirty miles of BRMC, and will not provide other outpatient diagnostic imaging services within thirty miles of BRMC while the proposed "under arrangements" joint venture is in development or give BRMC a right of first refusal for any other competing diagnostic imaging services if the "under arrangements" venture is not implemented. (Id. at §14.)

The parties did not seek or obtain an advisory opinion on the legality of the arrangement from the Office of the Inspector General before entering into the Equipment Sublease. (BRMC 30(b)(6) Dep. at 191.)

The purpose of the Sublease Agreement and the Equipment Sublease was not simply to acquire a piece of equipment. (30(b)(6) Dep. at 140, 146, 154-157; Leonhardt Dep. at 57.) Mr. Leonhardt expected BRMC would get substantial referrals from Drs. Vaccaro and Saleh as a result of the sublease. (BRMC 30(b)(6) Dep. at 146, 154-156; Leonhardt Dep., at 57.) Mr. Leonhardt stated in reply to a hypothetical question that he would not have entered into the sublease arrangement if he knew that BRMC would not receive any referrals from Drs. Vaccaro and Saleh. (Leonhardt Dep. at 53.)

When the Equipment Sublease was entered into, there were only about three years left in the term of V&S's primary lease with GE. (BRMC 30(b)(6) Dep. at 144.)

The Equipment Sublease stated that "[s]ubsequent to the execution of this Sublease, the Equipment will be moved to the Sublessee [BRMC]." (Equipment Sublease, at 4.) Mr. Leonhardt believed that other physicians would not want to have their diagnostic work done at V&S's office. (Leonhardt Dep. at 40.)

Although the Sublease stated that the GE camera would be delivered to BRMC, the camera remained in V&S's offices. (BRMC 30(b)(6) Dep. at 74-75; Saleh Dep. at 152, 153.) BRMC paid V&S \$2,500 per month in rent, as well as payments for secretarial and other administrative expenses (on top of the Equipment Sublease payments) to keep the camera at V&S's offices. (Saleh Dep. at 152-158.)

Following the execution of the Equipment Sublease, BRMC paid V&S a billing fee equal to 10% of all collections for tests performed on the GE camera. (Saleh Dep. at 152-154.)

Based upon its collections, V&S billed BRMC the following amounts for billing services:

<u>Statement Date</u>	<u>Amount</u>
November 2003	\$2,492.23
December 2003	\$2,764.27
January/February 2004	\$4,243.84
March 2004	\$2,926.83
April 2004	\$817.33
June 2004	\$3,075.57

(Saleh Dep. at 151-160; V&S Medical Associates Billing Documents, Oct. 2003-June 2004, attached as doc. 41 to Relators' Appx.)

In connection with its use of the GE camera following execution of the Equipment Sublease, V&S made actual payments to BRMC (after deductions for space rental, 10% billing fee, and other charges) of the following amounts:

\$4,593.94 (November 2003)
\$4,317.68 (December 2003)
\$7,652.33 (February 2004)
\$6,715.37 (March 2004).

For the October 2003 invoice, BRMC made a net payment to V&S of \$4,879.84. The final invoice in June 2004 showed an amount due from BRMC of \$1,090.29. (Saleh Dep. at 151-160; V&S Billing Documents, Oct. 2003-June 2004.)

The GE camera was used for four or five months, through about March 2004, after which it was not used to perform nuclear tests. (Leonhardt Dep. at 78; Saleh Dep. at 158.)

At the time it entered into the sublease, BRMC had one nuclear camera of its own, and wanted to obtain a second camera. Mr. Leonhardt acknowledged, however, that BRMC did not need three cameras. (Leonhardt Dep., at 49-50.) BRMC did not believe that the GE camera was suited to its long-term needs, and knew that it would shortly replace the GE camera with another camera. (BRMC 30(b)(6) Dep. at 74-78; Leonhardt Dep. at 49, 78.)

BRMC avers that during sublease negotiations the hospital had determined that it would replace the GE Equipment with a new nuclear cardiology camera. According to BRMC, it was because the hospital was anticipating acquiring a new camera that the GE Equipment was never relocated to BRMC in accordance with the Sublease Agreement and the Equipment Sublease. Additionally, Defendants allege that because the GE equipment was not moved, BRMC and V&S entered into a separate agreement for temporary use of the space and services of V&S by BRMC. BRMC explains that the space and services agreement came into effect by way of a “proposal” letter from V&S, along with a V&S invoice. Defendants claim that BRMC agreed to the proposal letter when BRMC’s then Chief Financial Officer “approved and executed” the V&S invoice. (BRMC’s Concise Statement of Facts, at ¶ 19 ; V&S Defendants’ Concise

Statement of Facts, at ¶ 21.) Relators dispute that Defendants entered into a space and services agreement.

On April 6, 2004, V&S entered into a five-year lease with Philips Medical Capital LLC, for a CardioMD Nuclear Camera, with a monthly rental fee of \$4,450.40 (adjusted periodically). (Master Lease Agreement between V&S Medical Associates and Philips Medical Capital LLC, April 6, 2004, and Master Lease Schedule No. 01.) In addition, Philips paid approximately \$200,000 to GE as an early termination fee to buy out the GE lease. (Master Lease Schedule No. 02 to Master Lease Agreement, April 16, 2004.) V&S agreed to repay this amount in 60 monthly installments of \$3,958.13 (adjusted periodically). (Id.) BRMC executed a guaranty of V&S's obligations to Philips. (Guaranty to Master Lease Agreement, April 6, 2004, and Addendum to Guaranty, April 22, 2004.)

Since the execution of the Philips lease documents, BRMC has reimbursed V&S for its payments under the Philips lease, and has also reimbursed V&S for its payments to Philips relating to the buyout of the GE camera. (Leonhardt Dep. at 81-85, 89.) In addition, BRMC pays V&S \$2,299.14 per month for a Philips service agreement. The payments for the Philips camera and Philips service agreement were scheduled to run through January 2010; the payments for the buyout of the GE camera ran through December 2009; and the non-compete payments under the Equipment Sublease ran through September 30, 2008.

Although the lease agreement was between Philips and V&S, the Philips camera was not placed in V&S's office because the lease specified that the camera would be located at the hospital. (Master Lease Schedule No 01, at ¶ 2; Leonhardt Dep. at 80; Saleh Dep. at 52.) BRMC and V&S did not enter into a written sublease agreement with respect to the Philips camera. (Leonhardt Dep. at 89; Saleh Dep. at 52-53.) We note that this is a major point of

contention between the parties as Defendants contend that the October 1, 2003 Equipment Sublease is the written sublease agreement between BRMC & V&S regarding the Philips camera. Defendants argue that Section 5 of the Equipment Sublease contemplated and provided for the effects of a change or upgrade in equipment.

Upon the early buyout of the GE lease, V&S obtained ownership of the GE camera, and in December 2006, made a charitable donation of the GE camera to Hamot Medical Center. (Letter from Drs. Vaccaro and Saleh to Hamot Medical Center, Dec. 11, 2006; Letter from Hamot Medical Center to Drs. Vaccaro and Saleh, Dec. 12, 2006.)

Since at least January 1, 2006, Dr. Saleh has had a contract with BRMC to serve as a Case Management Medical Director, for which he is paid \$2,000 per month by BRMC. (Saleh Dep. at 173-174, 175-176.) Dr. Saleh testified that he had a similar contract for a period of time before January 1, 2006, although he could not remember how long before. (Saleh Dep. at 175.) In addition, since at least March 1, 2006, Dr. Saleh has had a separate contract with BRMC to provide certain internal medicine services for Bradford Recovery Systems, for which he is paid a specified amount. (Saleh Dep. at 171-172, 175-176.) Dr. Saleh testified that he might have had a similar agreement prior to March 1, 2006. (Saleh Dep. at 172-173.)

Since at least March 1, 2006, Dr. Vaccaro has had a contract with BRMC to provide certain internal medicine services for Bradford Recovery Systems, for which he is paid \$2,000 per month. (Vaccaro Dep. at 50-52.) Dr. Vaccaro testified that he might have had a similar contract for a prior year. (Vaccaro Dep. At 52.)

BRMC has submitted numerous claims to Medicare for inpatient and outpatient hospital services, and has received payment for such claims, where Drs. Vaccaro or Saleh were identified as the attending physician in box 82 of the UB-92 claim form. (Responses to Relators' Second

Request for Admissions to BRMC, Request No. 1.) Such claims were submitted electronically using the UB-92 format. (BRMC 30(b)(6) Dep. at 12-17, 26.) For inpatient claims, the “attending” physician is the same as the admitting physician. (BRMC 30(b)(6) Dep. at 18.) For outpatient claims, the “attending” physician is the same as the ordering physician. (Id.)

Relators allege that BRMC sought to gain substantial patient referrals for diagnostic nuclear imaging from Drs. Vaccaro and Saleh and V&S. Drs. Vaccaro and Saleh had a history of referring patients to BRMC for nuclear imaging until they invested in their own General Electric nuclear camera. With their own camera they no longer needed to refer patients to BRMC for imaging. BRMC threatened to revoke the doctors’ hospital privileges, which led to lengthy negotiations. Eventually, BRMC and the V&S Defendants entered into an arrangement whereby BRMC would sublease the GE camera from V&S. BRMC’s monthly sublease payments consisted of a “pass-through” amount to lease the camera (equal to the amount V&S owed GE under its lease) and an additional amount for a covenant not to compete. Relators claim that this arrangement was designed so that BRMC would obtain patient referrals from V&S and Drs. Vaccaro and Saleh in return for payments in violation of the law.

In support of their claim that the sublease was intended to gain patient referrals, Relators allege the following:

- the GE camera, which BRMC was paying for, remained at V&S’s office;
- because the camera remained at V&S’s office, BRMC paid an additional amount to V&S for rent and other expenses;
- BRMC also paid V&S a 10% fee for handling the billing and collections on behalf of BRMC for tests performed on the GE camera while it remained at V&S’s office;
- the parties ceased using the GE camera when V&S leased a new nuclear camera from Philips, although the Philips camera was located at BRMC;

- as part of the lease with V&S, Philips bought out the remainder of V&S's GE lease for \$200,000 in exchange for monthly payments from V&S; however, BRMC executed a guaranty on the payments and in fact did make the payments for the GE lease buyout;
- in addition to BRMC continuing to make payments on the GE sublease even though the GE camera was no longer being used, BRMC also made payments for V&S's lease for the Philips camera and a service agreement;
- despite BRMC's payments to V&S on the sublease, and the buyout of the GE lease, the GE camera remained in possession of V&S until they gave it away as a charitable donation;
- there is no signed written agreement between the parties for (i) payment of the rent and other expenses; (ii) the 10% collection fee; (iii) payment for the Philips camera and service agreement; or (iv) the buyout of the GE lease.

Defendants deny that their arrangement was unlawful. Defendants explain that their arrangements were a reasonable and fair resolution to a dispute, and do not require the doctors to refer patients to BRMC. According to Defendants, their arrangement does not meet the definition of a prohibited direct or indirect "financial relationship." Defendants allege, among other things, that compensation from the arrangement did not vary with or take into account the volume or value of referrals from Drs. Vaccaro and Saleh. In addition, even if their arrangement did meet the definition of a "financial relationship", it is still permitted as it falls within a statutory or regulatory exception.

Defendants also take exception to Relators' characterization of their relationship. Defendants maintain that the GE camera remained at V&S's office because BRMC intended to obtain a new camera, but acquisition of the camera was delayed longer than expected. Defendants also allege that the parties did enter into a written agreement for rental of V&S's space and use of V&S services. In addition, Defendants contend that the Philips camera replaced the GE camera pursuant to a provision in the GE sublease, and thus it was the written agreement regarding the sublease of the Philips camera.

Presently before the Court are cross-motions for summary judgment filed by the Relators (Doc. 110), BRMC (Doc. 113), and Drs. Vaccaro and Saleh and V&S (Doc. 124).

For the reasons that follow, we will deny Defendants' motions for summary judgment and grant in part and deny in part Relators' Motion for Summary Judgment.

II. Standard of Review

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c), Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). Summary judgment may be granted only if the moving party establishes that there exists no genuine issue of material fact and that it is entitled to judgment as a matter of law. Id. Summary judgment is appropriate only when the record evidence could not lead a reasonable jury to find for the non-moving party. Anderson v. Liberty Lobby Inc., 477 U.S. 242, 248-249 (1986). In evaluating a motion for summary judgment the court does not weigh the evidence or make credibility determinations. Reeves v. Sanderson Plumbing Products, Inc., 120 S.Ct. 2097, 2110 (2000). Rather than evaluating the evidence and determining the truth of the matter, the court determines whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. In reviewing the evidence, the court draws all reasonable inferences in favor of the non-moving party. Reeves, 120 S.Ct. at 1210; Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986).

III. Discussion

Relators allege that Defendants submitted claims to Medicare in violation of the Stark Act and the Anti-Kickback Act. Both the Stark Act and the Anti-Kickback Act prohibit a health care entity from submitting claims to Medicare based on referrals from physicians who have a

“financial relationship” with the entity, unless a statutory or regulatory exception (or “safe harbor”) applies. 42 U.S.C. §§ 1395nn(a)(1); 1320a-7b(b). “Falsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program is actionable under the FCA.” United States ex rel. Kosenke v. Carlisle HMA, Inc., 554 F.3d 88, 95 (3d Cir. 2009) (citing United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004) (other citations omitted). Section 3729 of the False Claims Act imposes liability, in relevant part, on any person who:

- (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

31 U.S.C. § 3729(a)(1)-(2).

Relators seek judgment as a matter of law on all their claims. In the alternative, Relators seek partial summary judgment on the following issues:

1. A financial relationship existed between BRMC and Drs. Vaccaro and Saleh pursuant to the Stark Act;
2. None of the exceptions under the Stark Act apply to Defendants;
3. BRMC offered and paid remuneration to the V&S Defendants, and the V&S Defendants solicited and accepted such remuneration as an inducement or reward for referrals of medical services payable under federal healthcare programs in violation of the Anti-Kickback Act;
4. None of the “safe harbor” provisions under the Anti-Kickback Act apply to Defendants;
5. BRMC submitted claims for payment to Medicare based on referrals from Drs. Vaccaro and Saleh pursuant to the Stark and Anti-Kickback Acts, and received payment from Medicare for such claims;
6. V&S Defendants caused the submission of such claims; and

7. Defendants acted knowingly, as that term is used in the False Claims Act.

BRMC and the V&S Defendants move for summary judgment and dismissal of the Complaint, arguing that judgment as a matter of law is appropriate with respect to the following:

1. There is no direct or indirect financial relationship between BRMC and either Dr. Vaccaro or Dr. Saleh as defined by the Stark Act and accompanying regulations;
2. Even if Defendants' financial relationship were considered to fall within the Stark Act, the relationships are permitted under the exceptions of the Stark Act;
3. Any financial relationship between BRMC and V&S and/or Drs. Saleh and Vaccaro do not violate the Anti-Kickback Act because the relationships fit within the applicable safe harbor provisions of the Act;
4. BRMC made no certifications of compliance with the Stark Act or Anti-Kickback Act when it submitted claims to Medicare, Medicaid, or any other federal health care program, and the Stark Act only applies to claims submitted to Medicare and Medicaid;
5. The V&S Defendants have not made any false or fraudulent claims for payment, and have not used or made a false record or statement, to the Government, nor did they have any reason to believe that their actions would or could cause the filing of a false claim or use of a false record or statement;
6. The V&S Defendants do not possess the required scienter for any violation of the False Claims Act.

We begin with the Stark Act. We will first determine if a financial relationship exists between BRMC and Drs. Vaccaro and Saleh, either direct or indirect, which “trigger[s] the restrictions by the Stark and Anti-Kickback Acts on the submissions of claims for services rendered following ‘referrals’ by a physician having a ‘financial relationship’ with the service provider.” Kosenke, 554 F.3d at 91. If a financial relationship exists, we then must determine whether any exception applies that permits the relationship. If no exception applies, we then turn to the issues of whether BRMC has submitted claims for designated health services based upon referrals from Drs. Vaccaro and Saleh, and the amount of damages.

Next, we examine the Anti-Kickback Act, keeping in mind that the requirements of the Anti-Kickback Act and its implementary regulations are for the most part the same as the Stark Act. Here, we must determine if the payments by BRMC were knowingly intended to induce or reward referrals, and if so, whether any of the Act's safe harbor provisions apply. Finally, we examine whether Defendants acted "knowingly" for purposes of the False Claims Act.

A. The Stark Act

Section 1395nn(a)(1) of the Stark Act provides in relevant part as follows:

If a physician . . . has a financial relationship with an entity specified in paragraph (2), then (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn(a)(1). For the present parties this means that if Dr. Saleh and/or Dr. Vaccaro have a financial relationship with BRMC, then the Doctors may not make a referral to BRMC for the furnishing of designated health services. Additionally, BRMC may not present a claim to Medicare or Medicaid (or other certain entities) for designated health services furnished pursuant to a prohibited referral from the Doctors.

1. Financial relationship

"Under the Act, a physician has a 'financial relationship' with an entity if the physician has 'an ownership or investment interest in the entity,' or 'a compensation arrangement' with it." Kosenke, 554 F.3d at 91, citing 42 U.S.C. § 1395nn(a)(2). A "compensation arrangement" is defined as "any arrangement involving any remuneration between a physician . . . and an entity." 42 U.S.C. § 1395nn(h)(1)(A). Similarly, the Stark regulations define "compensation arrangement" as "any arrangement involving remuneration, direct or indirect, between a

physician . . . and an entity.” 42 C.F.R. § 411.354(c). “Remuneration,” in turn, is defined under the Stark Act as “any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.” 42 U.S.C. § 1395nn(h)(1)(B).

a. Direct Financial Relationship

Relators argue that a direct financial relationship exists between BRMC and Dr. Vaccaro and Dr. Saleh. First, Relators argue that a direct financial relationship exists because the sublease arrangement is not just between BRMC and V&S, but it is also between BRMC and Drs. Saleh and Vaccaro individually because they both signed the agreements as individuals. Relators further argue that Drs. Saleh and Vaccaro each received remuneration from the arrangement due to BRMC relieving each of them from their personal liability for the GE lease.

In addition to the above arguments, Relators also argue that as a result of a change in the Stark regulations, a direct financial relationship exists between the parties without reference to the definition of remuneration as of December 4, 2007 (the date the new Stark regulation took effect).

Finally, Relators argue that a direct financial relationship exists between BRMC and each of the doctors because they each have personal service contracts with the hospital.

i. Drs. Saleh and Vaccaro individually

Relators claim that there is a prohibited direct financial relationship in the sublease arrangements by virtue of the fact that Dr. Saleh and Dr. Vaccaro each individually signed the April 16, 2003 Sublease Agreement, agreeing to be bound by its terms, and each doctor individually signed the October 1, 2003 Equipment Sublease, agreeing to be bound by the non-compete provisions of Section 14 of the Agreement. Relators further argue that the Doctors received “remuneration,” as defined in the Stark Act, from the arrangement with BRMC because

it relieved Dr. Saleh and Dr. Vaccaro from their personal liability under their guaranties to GE for the GE camera.

Defendants first assert that just because the doctors signed the Equipment Sublease in their individual capacity it does not mean that the doctors are parties to the Sublease in their individual capacity. However, Defendants offer no support for this assertion. We take Defendants failure to argue their position as a concession that the doctors are parties to the sublease arrangements in their individual capacity.

Defendants instead argue that even if the doctors are considered as parties to the Sublease, there is no direct financial relationship because the payments were made by BRMC to V&S, not to Dr. Saleh or Dr. Vaccaro as individuals. It is true that direct payment under the sublease arrangements was made to V&S, not to the doctors individually. However, the concern under the Stark Act is whether the arrangement with Dr. Saleh or Dr. Vaccaro involved “*any remuneration between*” the doctors individually and BRMC. 42 U.S.C. § 1395nn(h)(1)(A) (emphasis added).

The Stark Act defines remuneration as “any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.” 42 U.S.C. § 1395nn(h)(1)(B). In addition, the Stark regulations further explain that remuneration “means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind,” 42 C.F.R. 411.351. Thus, we do not only look to the direct and overt remuneration payments in cash under the sublease arrangements, but also to any indirect or covert payment (or other benefit) that the doctors may have received. Relators submit that Dr. Saleh and Dr. Vaccaro received remuneration in the form of BRMC’s payment on the GE lease and guaranty on the GE buyout because this action benefitted the doctors as they had each individually guaranteed V&S’s obligations to GE.

Relators specifically argue that the doctors received a substantial economic benefit as a result of BRMC guaranteeing the \$200,000 buyout of the GE lease.

Defendants disagree claiming that the lease payments under the sublease arrangements only created the “incidental effect” of preventing GE from pursuing Drs. Saleh and Vaccaro under their guarantee obligations. Moreover, Defendants argue that any benefit they did receive as a result of the pass-through payments occurred by virtue of the benefit “flowing through” V&S.

Defendants do not clearly address the fact that Dr. Saleh and Dr. Vaccaro each individually benefited from BRMC’s guaranty on the \$200,000 GE lease buyout. Pursuant to the sublease arrangements BRMC subleased the GE nuclear camera from V&S for a five-year period (even though there were only three years left on V&S’s lease with GE). Before the five-year period expired BRMC executed a guaranty on the buyout of the GE lease, and in fact made payments on that guaranty. Thus, Dr. Saleh and Dr. Vaccaro received the benefit of a guaranty that relieved them of a personal liability they owed of \$200,000. In addition, even though BRMC made the payments on the GE Camera, BRMC permitted V&S to retain possession of the camera. V&S then made a charitable donation of the camera to another hospital.

Defendants claim that had BRMC not made the payments under the guaranty, the doctors would have remained personally liable for the payments. To accept this argument would require that we ignore the actual benefit a party receives from a third-party guaranty. We find that this is not an incidental benefit, but rather a substantial benefit that qualifies as remuneration under the Stark Act and regulations. Accordingly, we can conclude that a direct financial relationship existed between BRMC and Dr. Saleh and Dr. Vaccaro individually for the period of time the sublease arrangement was in effect.

ii. The December 4, 2007 Regulations

Prior to December 4, 2007, the Stark regulations did not separately define “direct compensation arrangement,” but did include a definition for an “indirect compensation arrangement.” 42 C.F.R. § 411.354(c)(2). The definition of an “indirect compensation arrangement” requires that the aggregate compensation received by the physician “varies with, or otherwise reflects [or ‘takes into account’], the volume or value of referrals or other business generated by the referring physician for the entity furnishing the D[esignated] H[ealth] S[ervices].” 42 C.F.R. § 411.354(c)(2)(ii). If the remuneration flows directly to the physician, however, the relationship is a direct compensation arrangement. Therefore, prior to the December 4, 2007 change in the Stark regulations, a physician could avoid creating a “direct compensation arrangement” simply by making sure that any remuneration was paid to a professional practice rather than to the doctor individually. To the extent this was a “loophole,” it was closed by the Stark Phase III regulations, which provide that a physician can “stand in the shoes” of his practice.

The definition of “direct compensation arrangement” in the new regulations is as follows:

- (1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician . . . and the entity furnishing DHS without any intervening persons or entities.
- (ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to stand in the shoes of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if –
 - (A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and
 - (B) The physician has an ownership or investment interest in the physician organization.

42 C.F.R. § 411.354(c)(1). Under this definition some arrangements that may not have qualified as an “indirect compensation arrangement” under the prior definition requiring that the remuneration vary with or otherwise reflect (or take into account) the volume or value of referrals, are now considered “direct compensation arrangements” without any need for an examination of whether the remuneration varies with or otherwise reflects referrals.

Relators assert that since the effective date of the “stands in the shoes” provision, a direct financial relationship existed between BRMC and the doctors. Defendants respond by arguing that the sublease arrangement between the parties is permitted pursuant to the grandfather clause of the new regulation. The Stark regulations set forth a grandfather clause providing that the “stands in the shoes” provision “[n]eed not apply during the original term or current renewal term of an arrangement that satisfied the requirements of § 411.357(p) as of September 5, 2007.”

42. C.F.R. § 411.354(c)(3)(ii)(A). Defendants argue that the sublease arrangement fits within the exception set forth in § 411.357(p) and is thus grandfathered in as of the effective date of the regulation. In addition, Defendants argue that since the Equipment Sublease expired in September 2008, the “stands in the shoes” provision cannot apply since the arrangement no longer exists.

Defendants’ “grandfather” argument assumes that the sublease arrangements satisfy the exception set forth in § 411.357(p) for an *indirect* financial relationship. Relators argue that the sublease arrangements do not satisfy the exception. Relators also argue that BRMC and V&S were engaged in a financial relationship beyond September 2008, based on BRMC’s payments on the Philips lease and payments on the buyout of the GE lease. Thus, even though the sublease expired, Relators argue that the financial relationship continued and was therefore subject to the

“stands in the shoes” provision. Relators also argue that these post-sublease financial arrangements similarly do not satisfy the exception set forth in § 411.357(p).

As discussed below we find that the exception in § 411.357(p) does not apply to the sublease arrangements, and therefore Defendants cannot take advantage of the grandfather clause. Accordingly, the financial relationship between the parties was a direct financial relationship as of the effective date of the “stands in the shoes” provision.

iii. Personal Service Contracts

Finally, Relators claim that the doctors’ personal service contracts with the hospital create a direct financial relationship. We agree with Defendants that the mere fact that the doctors had separate personal service contracts with the hospital is insufficient to show a direct financial relationship that would fall within the Stark Act. Relators have not shown that these contracts are exceptional in any way that would relate to the Stark Act, and have not specifically related these contracts in any way to the False Claim allegations of their Complaint.

b. Indirect Financial Relationship

Relators also argue that an indirect financial relationship exists between BRMC and Drs. Saleh and Vaccaro. The definition of an “indirect compensation arrangement” requires (i) that there exists an unbroken chain of persons or entities that have financial relationships between them; (ii) that the aggregate compensation received by the physician varies with, or otherwise reflects or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the Designated Health Services; and (iii) the entity furnishing Designated Health Services has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the physicians aggregate compensation varies with, or

otherwise reflects or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity. 42 C.F.R. § 411.354(c)(2)(i)-(iii).

The parties agree that the financial relationships between BRMC and V&S are part of an unbroken chain between BRMC and Drs. Saleh and Vaccaro. They disagree on the remaining two elements.

Relators argue that there are two independent “indirect compensation arrangements.” First, Relators argue that the aggregate compensation from BRMC to V&S under the sublease arrangements “takes into account” or “otherwise reflects” the anticipated referrals from Dr. Saleh and Dr. Vaccaro.

Relators also argue that there is a separate “indirect compensation arrangement” between BRMC and V&S for the time period from October 2003 through approximately June 2004 when BRMC paid V&S a billing fee equal to 10% of all collections for tests performed on the GE camera. Relators maintain that this 10% fee directly varied with the number of referrals because as more referrals for tests on the GE camera were performed, more money was collected for the services, and thus the collections fee paid by BRMC to V&S increased in direct proportion to the increase in referrals.

We address the two separate compensation arrangements in turn.

i. The Sublease Compensation Arrangements

Relators assert that the aggregate compensation received by the physicians otherwise reflects or takes into account the volume or value of referrals generated by the referring physicians for BRMC. Specifically, they argue that the compensation took into account anticipated referrals from Dr. Saleh and Dr. Vaccaro.

In general, BRMC and the V&S Defendants argue that no indirect financial relationship under the Stark Act exists because the payments from BRMC to V&S are flat payments that do not vary with the amount of referrals from the doctors, the payments were otherwise at fair market value, and the compensation arrangement reflected a sensible, prudent business arrangement. Even if an indirect financial relationship was found, Defendants argue that their arrangements were permitted by the exceptions of the Stark Act. Before turning to the primary issue of whether an indirect compensation arrangement exists, we address three preliminary issues.

Defendants first argue that there can be no unlawful indirect compensation agreement because the payments by BRMC to V&S are fixed and do not fluctuate based on the number of patients referred to BRMC by Drs. Saleh or Vaccaro. Of course it is a fact that the *fixed* aggregate compensation under the sublease arrangements does not vary up or down with referrals. However, the question remains whether the aggregate compensation “takes into account” or “otherwise reflects” the volume or value of referrals.

Next, Defendants claim that the proper relationship to focus on when determining whether the aggregate compensation varies with or takes into account the volume or value of referrals is the relationship between V&S and Drs. Saleh and Vaccaro. In other words, Defendants maintain that we examine the compensation that flows from V&S to the doctors. Relators claim that the correct relationship under the law concerns the compensation from BRMC to V&S.

The determination of whether compensation varies with or takes into account referrals for the entity providing Designated Health Services is “measured by the nonownership or noninvestment interest closest to the referring physician.” 42 C.F.R. § 411.354(c)(2)(ii). Drs.

Saleh and Vaccaro have an ownership interest in V&S, which has a compensation arrangement with BRMC, and thus the nonownership or noninvestment interest closest to the doctors is BRMC. See also 66 Fed. Reg. at 866 (For ownership or investment interests the inquiry is “whether the aggregate compensation the owned entity [V&S] receives varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS [BRMC]”). Thus, the applicable Stark regulation and its interpretation unequivocally show that the correct relationship is between BRMC and V&S. 42 C.F.R. § 411.354(c)(2)(ii).

Finally, Relators argue that “anticipated referrals” is a proper basis for a finding that compensation takes into account the value or volume of referrals by citation to the Stark regulations and to the Centers for Medicare and Medicaid Services (“CMS”) interpretation of the regulations. We agree.

In the regulations lengthy definition of “fair market value,” the definition states that a fair market price of assets or a fair market compensation for service exists “where the price or compensation has not been determined *in any manner* that takes into account the volume or value of *anticipated* or actual referrals.” 42 C.F.R. § 411.351(emphasis added).

In addressing the physician recruitment provisions, CMS include the following comment from the public:

One commenter objected to the conditions in § 411.357(e)(1)(iii) and (e)(4)(v) that the remuneration not directly or indirectly take into account the volume or value of actual or anticipated referrals or other business generated by the recruit or the physician practice, if it received any payments. According to the commenter, hospital recruitment arrangements always anticipate referrals to the hospital.

77 Fed.Reg. at 51048. CMS responded to this comment as follows:

We recognize that parties to a physician recruitment arrangement may anticipate some referrals by the recruited physician. In this context, the “volume and value” condition *prohibits the amount of assistance payable to the physician* or the group practice from taking into account, *in any manner*, the volume or value of past or *anticipated* referrals to the hospital. The unconditional payment of actual moving expenses, for example, would not take into account the volume or value of referrals.

Id. (emphasis added).

In the context of addressing its interpretation of the “value or volume standard” CMS stated as follows:

[W]e have determined that we will not consider the volume or value standard implicated by otherwise acceptable compensation arrangements for physician services solely because the arrangement requires the physician to refer to a particular provider as a condition of payment. So long as the payment is fixed in advance for the term of the agreement, is consistent with fair market value for the services performed (that is, the payment does not take into account the volume or value of the *anticipated* or required referrals), and otherwise complies with the requirements of the applicable exception, the fact that an employer or a managed care contract requires referrals to certain providers will not vitiate the exception.

66 Fed.Reg. at 877(emphasis added). Similarly, the regulation that addresses the physician’s compensation exception states that the compensation may be conditioned on the physician’s referrals so long as it meets all of the enumerated conditions, including that the compensation arrangement is “consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of *anticipated* or required referrals).” 42 C.F.R. § 411.354(d)(4)(ii) (emphasis added). Thus we conclude that “anticipated referrals” are a proper consideration under the Stark Act.

We now turn to Relators’ argument that the compensation paid by BRMC to V&S takes into account referrals. In support of their argument, Relators bring to the Court’s attention the Report prepared by accountant Charles T. Day. (Report of Charles T. Day, undated, attached as Exhibit K to V&S Defendants’ Appendix; as Exhibit 16 to BRMC’s Appendix; and Exhibit 7 to

Relators' Appendix.) The Day Report was prepared at the request of BRMC prior to BRMC entering into the Equipment Sublease. Although the Report is undated, BRMC has verified that it was dated "right before [BRMC] entered into the agreement," and that it was prepared in order to evaluate the sublease arrangements and offer an opinion as to the fair market value of the arrangements. (Rule 30(b)(6) Dep., at 147, 148-149.)

In his Report, Mr. Day notes that the Board of BRMC wanted a covenant not to compete associated with the sublease in order to protect "three revenue streams": CT and MRI revenues, inpatient net revenues, and outpatient net revenues (not including CT and MRI revenues). (Day Report, at 14.) In his appraisal of the covenant not to compete, Mr. Day created a table to show the expected revenues BRMC would receive with the non-competition agreement in place, and compared those revenues to how much BRMC would pay under the non-compete agreement. (Id. at 17.) Mr. Day explained that his table is "based on the assumption that the Physicians would likely refer this business to the Hospital in the absence of a financial interest in their own facilities or services, although they are not required to do so by virtue of any of the covenants contained in the Agreements or otherwise." (Id.)

Therefore, the Report itself indicates that the analysis of whether the non-competition agreement represents a fair market value is based, in part, on anticipated referrals from the doctors. BRMC affirmed that the Report evaluated expected revenues based on the assumption that Defendants would likely refer the business to BRMC. (Leonhardt Dep. at 56.)

Mr. Leonhardt testified that he relied upon the Day Report's fair market value analysis in determining if the non-compete did represent a fair market value. (Leonhardt Dep. at 56.) Mr. Leonhardt further testified as follows:

Q. It's fair to say that the purpose of the noncompete agreement was to protect that revenue stream [referrals from Dr. Saleh and Dr. Vaccaro].

A. The purpose of the noncompete, from my point of view, was to make sure that Drs. Vaccaro and Saleh didn't have a financial incentive to refer away from the hospital.

Q. Because if they didn't have a financial incentive to refer away, they would refer it to you?

A. We could hope that they would, yes.

Q. You did more than hope. You expected they would refer to you?

A. Expected they would refer a good bit of it to us, yeah.

(Leonhard Dep. at 56-57.)

Before the Equipment Sublease could be entered into by BRMC, Mr. Leonhardt had to obtain Board approval. (Leonhardt Dep. at 66-67.) As part of his presentation to the Board seeking approval for the Equipment Sublease, Mr. Leonhardt relied on a written summary that showed expected profit for BRMC from entering into the lease agreement, where expected profit included a portion of business that would come from Drs. Saleh and Vaccaro. (Leonhardt. Dep. at 68-72; Exhibit 8 attached to Relators' Appendix.) Following the presentation the Board gave its approval for BRMC to enter into the Equipment Sublease. (Leonhardt Dep. at 72-73.)

We find that this evidence is sufficient to show that the aggregate compensation received by the physicians takes into account the volume or value of referrals generated by the referring physicians for BRMC.

In response to Relators' evidence, Defendants primarily rely on affidavits from George Leonhardt, Charles Day, and Mark Voydavich (the CEO of Stroudwater Associates, a consulting company engaged by BRMC). We have reviewed these affidavits and find nothing in them that would negate the above evidence that the compensation agreement took into account anticipated referrals.

Mr. Leonhardt describes how the amount of payments for the non-compete provision was arrived at as follows:

V&S proposed an amount which it represented to be equivalent to its profits from the operation of the nuclear camera in its office. BRMC then negotiated with V&S until the parties arrived at a lower amount that was acceptable to BRMC.

(Leonhardt Affidavit, Oct. 8, 2008, at ¶ 2.) At best, these statements explain the unremarkable situation that the parties had a back and forth negotiation before arriving at a price. As the Third Circuit Court of Appeals has explained:

[A]s a legal matter, a negotiated agreement between interested parties does not ‘by definition’ reflect fair market value. To the contrary, the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of non-fair-market-value compensation.

Kosenke, 554 F.3d at 97.

In addition, Mr. Leonhardt’s statement that V&S proposed an amount “represented to be equivalent to its profits from the operation of the nuclear camera” only confirms that the starting point for negotiations was the amount of business V&S thought it could generate for BRMC. The only way the proposed amount of business could end up with BRMC is if V&S referred that business to BRMC after BRMC leased the GE camera.

Mr. Leonhardt also states a legal conclusion in his affidavit opining that the payments under the sublease do not take into account the volume or value of anticipated referrals. (Id. at ¶ 3.) Next, Mr. Leonhardt testified that the purpose of the sublease was to enable BRMC to fulfill its charitable mission by providing needed cardiology services to the community, and that it was not the purpose of the sublease to induce referrals from the V&S Defendants. (Id. at ¶ 4.) No provision of the sublease arrangements, including the non-compete provision, explicitly requires referrals from the doctors. Nonetheless, Mr. Leonhardt’s testimony does not negate the evidence showing that the arrangement “took into account” anticipated referrals.

Defendants also submit that the amounts paid pursuant to the sublease were determined by agreement of the parties prior to Mr. Day's report, and prior to Mr. Leonhardt's presentation to the Board, and thus the payments were not based either on Mr. Day's report or on the projections provided to the Board. (Leonhardt Affidavit, at ¶¶ 5,6 ; Day Affidavit, Oct. 8, 2008, at ¶ 4.) These statements, however, do not counter the record evidence that the analysis in the Day Report was "based on the assumption that the Physicians would likely refer this business to the Hospital" and that Mr. Leonhardt's summary presentation showed an expected profit for BRMC from entering into the lease agreement that was based on receiving business from V&S. The fact that the parties had agreed upon the amount of payments before the Day Report and Board Presentation only shows that the parties were aware of the value of the non-compete based on the amount of business BRMC might gain from V&S.

Additionally, Defendants contend that the projected numbers prepared by Stroudwater Associates and Mr. Day's projected effect on BMRC's cash flow prepared when analyzing the non-compete provision were based on "what BRMC would have lost" had it decided to terminate Dr. Saleh and Dr. Vaccaro's medical staff appointment and clinical privileges pursuant to its Policy. (Voydavich Affidavit, Oct. 9, 2008, at ¶¶ 5, 7, & 8; Day Affidavit, at ¶ 7; Defendants' Joint Opposition, at 10.) However, this interpretation supports Relators' contention that the compensation arrangement took into account anticipated referrals as "what BRMC would have lost" is, in part, Dr. Saleh and Dr. Vaccaro's business, that is, the doctors' anticipated referrals.

Defendants' primary response to Relators' argument is that Relators have failed to show with record evidence that the compensation arrangement is not fair market value. Defendants argue that the compensation arrangement, pursuant to a "bright line" rule, does not take into account referrals. Defendants further argue that Relators have the burden to prove that the

presumptively valid compensation arrangement is not fair market value, and Relators have failed to meet their burden.

Consistent with their position that the burden of proof lies with Relators in the first instance, Defendants do not put forth any evidence regarding fair market value in their main briefs. In Defendants' Joint Opposition to Relators' Motion for Summary Judgment, they again assert that the Relators "have the burden of showing that the amounts paid do not reflect the fair market value." (Defendants' Joint Opposition, at 9.) Similarly, in BRMC's Reply Brief, it states that Relators bear the burden of proving [fair market value] in order to show a financial relationship covered by the Stark Act, and have offered no evidence as to the fair market value of the payments from BRMC to V&S." (BRMC Reply Brief, at 5.) We note that even when arguing that an exception applies to the compensation arrangement, Defendants still do not set forth any record evidence, as opposed to argument and a general citation to their expert report, showing that the arrangement is consistent with fair market value. We will discuss Defendants' fair market value argument after first examining Defendants' argument regarding the "bright line" rule and the proper burden of proof for establishing fair market value.

BRMC argues that there exists a "bright-line rule" for determining whether compensation takes into account referrals and that the Equipment Sublease satisfies this rule.

Defendants assert that the "bright-line" rule states:

A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated.

66 Fed. Reg. at 877-878. Defendants also rely on United States ex rel. Villafane v. Solinger, 543 F.Supp.2d 678 (W.D.Ky. 2008), in which the Court stated:

[W]here no violation appears on the face of the arrangement, either in the form of above-fair-market value compensation or of a provision allowing for increases or decreases in payment based on the number of referrals made, the text and history of the Stark law's desire to create a "bright-line rule" would seem to argue against establishing a violation on the basis of intent alone.

Id. at 693.

Defendants argue that their arrangement satisfies this rule because the payments under the sublease are fixed and the agreement was commercially reasonable. (BRMC Brief in Support of Motion for Summary Judgment, at 10-11, citing, *inter alia*, 69 Fed.Reg 16093 & 66 Fed. Reg. 878-879.) Moreover, Defendants argue that the payments were not above fair market value because the non-compete provision was a sensible, prudent business arrangement, and the non-compete is permissible as a provision that does not require Drs. Saleh or Vaccaro to refer patients to BRMC. (Id.)

The "bright-line rule" relied upon by Defendants appears in CMS's Phase I implementing regulations. See *Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships*, 66 Fed. Reg. 855.

In section V of Phase I's implementing regulations, which is where the "bright line" rule appears, CMS addressed "'Volume or Value' of Referrals and 'Other Business Generated' Standards." In this section, CMS was specifically addressing the exceptions portion of the Stark Act.

The CMS statement confirms that with respect to an agreement where the compensation is fixed in advance, such as the Equipment Sublease, the fixed compensation must result in fair market value. If the "fixed payment is in excess of fair market value, *i.e.* if it includes some sort of payment above and beyond the market value of the physician's services," then the fixed payment may be determined to "take into account the volume or value of any referrals."

Villafane, 543 F.Supp.2d at 693 (interpreting the above-quoted CMS statement, 66 Fed. Reg. at 877-878). Thus, the CMS statement directs us to an assessment of the fair market value of the aggregate compensation under the Equipment Sublease. Relators in fact base their argument that the compensation provided under the Equipment Sublease takes into account referrals by setting forth their analysis of whether the Equipment Sublease reflects “fair market value.” The “bright-line rule”, however, is misnamed at least insofar as it does not provide a “bright line” regarding “fair market value.” Once the fair market value of an arrangement is determined it would seem that application of the bright line rule is fairly straightforward. Determination of fair market value, however, will not typically be so simple.

The parties have two competing positions regarding the fair market value issue. Relators’ position is that we do not address fair market value until a defendant asserts an exception, and that defendants have the burden of proving that an exception applies. Accordingly, Relators argue that we should first determine whether an indirect compensation agreement exists, which only requires an assessment of whether the compensation “takes into account” referrals, not an analysis of “fair market value.” Relators further argue that “fair market value” will only become relevant when a defendant is arguing that the compensation agreement fits into an *exception* under the Stark Act. Finally, Relators argue that a fixed aggregate compensation arrangement that takes into account referrals cannot be fair market value.

Defendants’ position is that because their fixed compensation arrangement is deemed to not take into account referrals under the “bright line” rule, the burden is on Relators to prove that the compensation arrangement is not fair market value in the first instance in order to show that the arrangement is an indirect compensation agreement. Defendants do not ignore the requirement that the fixed compensation must also result in fair market value, but instead

perform their analysis of the “fair market value” of the arrangement without assigning any significance to record evidence regarding the “fact that one or both of the parties may have considered referrals.” (Defendants’ Joint Opposition to Relators Motion for Summary Judgment, at 9.)

There is no clear-cut resolution to this question. However, reviewing the Stark Act, regulations, CMS’s implementing regulations, and case law together suggests that Relators are correct that the issue of whether a fixed compensation agreement is fair market value is not considered until Defendants raise it in defense as an exception.

Under the Stark Act we examine whether there is a prohibited financial relationship involving a compensation arrangement involving indirect remuneration, and such remuneration can be, as broadly described in the Act, overt or covert, in cash or in kind. 42 U.S.C. § 1395nn(a)(2), (h)(1)(A), and (h)(1)(B). To find an “indirect compensation arrangement,” the regulations require, as one element, that the aggregate compensation received by the physician varies with, or otherwise reflects or takes into account referrals. 42 C.F.R. § 411.354(c)(2)(ii). The logical structure of the Stark Act and applicable regulations therefore suggest that the proper order is to first determine whether an indirect compensation arrangement exists, meaning whether it satisfies the definition, before turning to the question of whether an exception applies. This straightforward interpretation means there is no fair market value analysis at the first stage of determining whether an indirect compensation arrangement exists.

It becomes less clear considering that CMS indicates that its interpretation of the volume or value standard, which uses the term “fair market value” often, should be applied uniformly.

The first instance when CMS mentions a uniform application clearly applies to exceptions:

For purposes of the new *exception*, in determining whether compensation takes into account the value or volume of referrals or other business generated by the

referring physician for the DHS entity, we will apply the tests for “volume or value of referrals” and “other business generated” that are discussed in section V of this preamble and set forth in § 411.354(d) of these regulations. This is consistent with our determination to interpret those phrases uniformly in all *exceptions* in which they appear.

66 Fed.Reg. 867 (emphasis added). In Section V, which as noted specifically addresses exceptions, CMS addressed the volume or value standard stating that it was “revising the regulation with respect to the scope of the volume or value standard.” 66 Fed.Reg. at 877. After setting forth its revisions, CMS explained:

Simply stated, [the Stark Act] establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician's ability to generate other revenues.

Id. Immediately following this statement, CMS stated:

In order to establish a ‘bright line’ rule, we are applying *this* interpretation of the volume or value standard uniformly to all provisions . . . where the language appears (for example, the employee, personal service arrangements, rental of office space/equipment, fair market value, non-monetary compensation under \$300, hospital medical staff benefits, academic medical center exceptions, indirect compensation arrangements, and the group practice definition).

Id. (emphasis added). The specific provisions listed by CMS are all exceptions, which makes sense in a section that is addressing the volume or value standard primarily in regard to exceptions.

The “bright line” rule itself is the interpretation of the volume or value standard CMS set forth in the implementing regulations just before it announced that it was applying “this interpretation” uniformly. In contrast, later in Section V, CMS responded to commenters who asked CMS to clarify whether four identified arrangements take into account the volume or value of referrals or other business generated between the parties.” 66 Fed.Reg. at 877. The four arrangements proposed by the commenters are: “(1) Payments based on a percentage of gross

revenues; (2) payments based on a percentage of collections; (3) payments based on a percentage of expenses; and (4) payments based on a percentage of a fee schedule.” It is CMS’s response to these commenters that Defendants cite as the “bright line” rule:

A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated.

66 Fed. Reg. at 877-878.

Defendants’ position, therefore, must be that the court should place primary importance on a response to a comment in the implementing regulations clarifying CMS’s interpretation of the volume or value standard, over the actual interpretation. In addition, Defendants’ argue that the definition of an “indirect compensation agreement” should be interpreted so as to require that any fixed compensation agreement must initially be shown by relators not to be fair market value, even though the definition does not include any language referring to fair market value.

The Villafane decision relied upon by Defendants is of limited guidance. In that case, the Court was deciding only the issue of whether the Academic Medical Center *exception* applied. Villafane, 543 F.Supp.2d at 680. As noted, nearly all exceptions, including the Academic Medical Center exception, include a requirement that the compensation arrangement not exceed fair market value. 42 C.F.R. § 411.355(e)(1)(ii)(B). Thus, the Villafane Court examined whether each of the Defendant physicians’ total compensation, which was a fixed amount, was fair market value. Villafane, 543 F.Supp.2d at 690-692. The Court placed the burden of proof for establishing eligibility for the exception on the defendant physicians, not on relators. Id. at 687. The defendant physicians offered documentary evidence to show that their salaries were consistent with salaries nationwide. Id. at 691. The Court considered the relators’ evidence and

their argument in response and ultimately determined that the physicians' salaries were set at fair market value.

Only then did the Villafane Court turn to the separate requirement of the Academic Medical Center exception that must be met: that the total compensation is not determined in a manner that takes into account the volume or value of referrals. Id. at 692. It is at this point that the Court made the statements regarding fixed compensation agreements relied upon by Defendants. It appears that the relators in the Villafane case argued that the mere existence of the fact that the physicians made referrals to the pediatric hospital that contributed monies to a fund that partially funded the physicians' salaries should be sufficient to show that the exception was not met; that is, that the fixed salaries "took into account" referrals merely because referrals occurred. Villafane, 543 F.Supp.2d at 692. Unsurprisingly, the Court disagreed. In doing so the Court noted that, according to CMS, a *fair market value* fixed payment compensation arrangement that does not vary over the term of the arrangement will not be considered to take into account the volume or value of referrals. Id. at 692-693, quoting 66 Fed.Reg. at 877-878.

The Villafane Court also explained that, pursuant to the CMS statement, a fixed payment compensation arrangement that does not vary over the term of the arrangement may be considered to take into account the volume or value of referrals, "only if that fixed payment is in excess of fair market value, *i.e.*, if it includes some sort of payment above and beyond the market value of the physician's services." Id. at 693. Defendants rely on the Villafane Court's subsequent statement that

where no violation appears on the face of the arrangement, either in the form of above-fair-market value compensation or of a provision allowing for increases or decreases in payment based on the number of referrals made, the text and history of the Stark law's desire to create a "bright-line rule" would seem to argue against establishing a violation on the basis of intent alone.

Id. at 693.

This statement by the Court shows that in order for a fixed compensation arrangement to satisfy the second requirement and qualify for the Academic Medical Center exception the arrangement (1) must not be above-fair-market value compensation, and (2) there must not be a provision allowing for increases or decreases in payment based on the number of referrals made. Once those requirements are met then it can be said that “no violation appears on the face of the arrangement” and the Court would not look for a violation based on intent alone. Id. More specifically, the Court would not examine whether it was the intent of the defendant Hospital to contribute to the fund that paid the physicians’ salaries *because* the physicians made referrals to the Children’s Hospital. Id. In Villafane there was no dispute that the compensation did not vary with referrals, and thus the only issue was whether the salaries were above fair market value, an issue the Court had already determined based on the record evidence. Had the defendants not been able to show in the first step that the physicians’ salaries were fair market value, presumably the Court would have found that because there was a fixed compensation agreement that was *above fair market value* it could not summarily conclude that the arrangement met the exception.

Considering the Villafane decision, the Stark Act, the Stark regulations, and CMS’ interpreting regulations, we conclude that the burden of establishing whether a fixed compensation arrangement is consistent with fair market value rests with the defendant when raising an exception.

We note that one of the first pieces of evidence Relators present to support their argument that the fixed compensation arrangement takes into account anticipated referrals is Defendants’ fair market value assessment of the sublease arrangement. However, Relators argument is not, at

least at this stage, an argument that the fixed compensation agreement is as a matter of law above “fair market value.” Rather, Relators submit evidence to support a straightforward conclusion that the arrangement takes into account referrals. On this issue, as we have discussed, Relators are convincing.

In any event, even if the burden of proof was with Relators we find that Relators have shown that the compensation arrangement is above fair market value.

The Regulations definition of Fair Market Value is as follows:

Fair market value means the value in arm’s-length transactions, consistent with the general market value. “General market value” means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), “fair market value” means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

42 CFR § 411.351. CMS also addressed the definition of “fair market value” providing the following additional guidance:

To establish the fair market value . . . of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in

arm's-length transactions who are not in a position to refer to one another. (As discussed in section V of this preamble, in most instances the fair market value standard is further modified by language that precludes taking into account the “volume or value” of referrals, and, in some cases, other business generated by the referring physician. Depending on the circumstances, the “volume or value” restriction will preclude reliance on comparables that involve entities and physicians in a position to refer or generate business.) The amount of documentation that will be sufficient to confirm fair market value . . . will vary depending on the circumstances in any given case; that is, there is no rule of thumb that will suffice for all situations. The burden of establishing the “fairness” of an agreement rests with the parties involved in the agreement.

66 Fed.Reg. at 944 (*Part VII. Definitions of the Designated Health Services, N. Other Definitions, 3. Fair Market Value*). Specifically addressing the “fair market value” exception, CMS noted the following:

With respect to determining what is “commercially reasonable,” any reasonable method of valuation is acceptable, and the determination should be based upon the specific business in which the parties are involved, not business in general.

66. Fed.Reg. at 919 (*VII. New Regulatory Exceptions, B. Fair Market Value (§ 411.357(l))*).

The final comment set forth in the section addressing the “fair market value” exception noted concern by commenters that by requiring that compensation not be related to the volume or value of referrals the regulations had undermined the usefulness of the fair market value exception. *Id.* In particular, one commenter suggested “that an arrangement should not pose a risk of abuse as long as the compensation does not reflect the volume or value of the physician's own referrals.” *Id.* We view this comment as essentially suggesting what Defendants here are arguing: a fixed compensation agreement that does not explicitly reflect the value or volume of referrals is permissible. CMS’s response to these comments, which conclude this section, was a terse referral to the section specifically addressing the value or volume standard:

For a discussion of the “value or volume of referrals” standard, refer to the discussion at section V of this preamble. We are conforming the language of the new fair market value exception to our uniform interpretation of the standard, which is discussed at section V of this preamble.

Id. We view CMS’s referral as a rejection of the commenter’s suggestion, essentially telling the commenter that “an arrangement *may* pose a risk of abuse *even if* the compensation does not reflect the volume or value of the physician's own referrals.”

Turning back to Section V, we revisit CMS’s uniform interpretation of the value or volume standard already discussed:

Simply stated, [the Stark Act] establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician's ability to generate other revenues.

66 Fed.Reg. at 877. Under this standard, as we have already discussed, a fixed payment compensation arrangement such as the one in this case may be considered as taking into account the volume or value of referrals “if that fixed payment is in excess of fair market value, *i.e.*, if it includes some sort of payment above and beyond the market value of the physician’s services.” Villafane, 543 F.Supp.2d at 693.

Defendant’s put forth as proof of fair market value, the expert report of James H. Jordan, in which Mr. Jordan concluded that amounts exchanged by the parties reflected the fair market value. Defendants then present their argument as to why the arrangements were fair market value. Defendants further argue that Relators have failed to counter Mr. Jordan’s report and can only “take potshots at the Defendants’ expert opinion . . . insufficient to create a genuine issue of material fact regarding fair market value.” (BRMC Reply Brief, at 6; see also id. at 7.) Finally, Defendants attack Relators’ expert for failing to offer an opinion as to the fair market value of the arrangement. They further note that Relators’ expert testified that he was not qualified to render an opinion on the fair market value of the amounts paid pursuant to the arrangements.

Although there are two expert reports, at least when it comes to the issue of “fair market value” there is no “battle of the experts” since Relators do not rely on their expert report to show that the compensation arrangement is not fair market value. Thus, Defendants are correct that Mr. Barbera did not offer an opinion on fair market value and he disclaimed having the expertise to render such an opinion. This is not a meaningful criticism of Mr. Barbera given Mr. Barbera’s area of expertise and the fact that Relators did not engage him in order to show fair market value. (Expert Report of Sal Barbera, April 30, 2008, at 4-5 (Mr. Barbera is a “veteran hospital administrator” and a Fellow in the American College of Healthcare Executives. He describes himself as a ‘consultant specializing in general hospital management, physician/hospital relationships, organizational structures, physician and hospital compliance with fraud and abuse regulations, and the outsourcing of government owned and operated healthcare treatment facilities”).)

While Defendants do rely on their expert’s report to show fair market value, they do little more than generally cite to the report in support of their argument. In BRMC’s primary Brief the only mention of the expert report is in support of arguing that a safe harbor exception applies because the payments were commercially reasonable. (BRMC Brief in Support, at 9 (“as evidenced in the Defendants’ expert report, the aggregate payments do not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental”).) In its Reply Brief BRMC cites to Mr. Jordan’s deposition to show the number of hours he spent reviewing documentation and financial information, and to show that he traveled to Bradford to conduct interviews, view equipment, and tour offices in preparing his report. (BRMC Reply Brief, at 7.) In their Joint Opposition Brief, Defendants cite to their entire expert report in support of their argument that Defendants have shown “fair market value” through an

appraisal by a qualified independent expert, noting that the “Defendants’ expert concluded that the amounts exchanged reflected the fair market value as defined in §411.351.” (Defendants’ Joint Opposition, at 9-10, citing Expert Report of James H. Jordan pp. 178-261.) However, Defendants never offer any specific citations to their expert’s report, never quote from the report, and do not offer explanations or interpretations of the expert’s report in support of their position that the compensation arrangements are fair market value.

Defendants’ argument appears to be that the compensation arrangement is “fair market value” because, as their expert concluded, the compensation amount of the non-compete payments is roughly equal to the amount of business that the doctors would refer to BRMC. Defendants claim that the amount was arrived at by each side (the doctors and the hospital) valuing what they would give up and what they would get by entering into the arrangement. Defendants further argue that the amount of compensation is not *above* the fair market value of what any referrals might be, and the compensation does not depend upon referrals. Defendants additionally note that under the arrangement the doctors would no longer have the threat of BRMC revoking their privileges, while BRMC would acquire a nuclear camera that it hoped would further their hiring of a full-time cardiologist. Mr. Jordan’s expert report is little more than a formalized report in line with Defendants’ argument, and thus is less helpful than Defendants have made it out to be.

It is clear that the hospital and the doctors entered into an agreement that was fair for each party. The significant exchange here is the non-compete payments that would require the doctors to not engage in the nuclear camera business. A “fair market value” to the doctors to get out of the nuclear camera business was roughly the amount of money they would make by staying in the business and referring their patients to their own camera. Similarly, to the hospital

“fair market value” to pay the doctors to get out of the nuclear camera business was roughly the amount of money they would expect to gain from the doctors no longer referring their patients to their own camera; which amount, unsurprisingly, is in the neighborhood of the business that would potentially be generated by the doctors referring their patients to the hospital for nuclear camera work.

While Defendants argue that there was a back and forth negotiation and that the non-compete agreement does not require the doctors to refer to BRMC, the amount of the non-compete payments took into account, in the common sense understanding of that phrase, the amount of referrals the hospital expected to gain from the doctors. There really is no dispute that the amount of the non-compete payments was arrived at by considering the amount of business BRMC would receive from the doctors. Although Defendants do not explicitly state that they “took into account” the anticipated referrals from Dr. Saleh and Dr. Vaccaro in arriving at the non-compete amount, a review of their briefs shows that Defendants implicitly concede that the value of the doctors’ anticipated referrals was a part of the negotiations.

In their Joint Opposition Brief, Defendants refer to “certain information that was taken into account by BRMC before entering into the Sublease”, and “simply considering the effect of referrals does not mean that the payments ‘take into account’ the volume or value of referrals.” (Defendants’ Joint Opposition, at 8.) In addition Defendants state that the “fact that one or both of the parties may have considered referrals does not mean that the price took those referrals into account.” (*Id.* at 9.) In BRMC’s Reply Brief, the hospital states that to the extent that payments are fixed “the fact that referrals may have been considered is irrelevant.”

(Reply Brief of BRMC, at 5.) Finally, BRMC conceded that “various documents and statements of the Defendants mention referrals,” but argue that mentioning referrals does not mean “the arrangement must take referrals into account.” (BRMC’s Brief in Support, at 9.)

We conclude that the compensation arrangement between BRMC and the doctors is “inflated to compensate for the [doctors] ability to generate other revenues.” 66 Fed.Reg at 877. Specifically, we find that the amount of the compensation arrangement was arrived at by taking into account the anticipated referrals from the doctors. We therefore conclude that the compensation arrangement between BRMC and the doctors is not “fair market value” under the Stark Act.

As Relators point out, the reason that section 411.351 defines “fair market value” of a compensation arrangement as the “result of bona fide bargaining between well-informed parties to the agreement *who are not otherwise in a position to generate business for the other party . . . where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals,*” is because a compensation arrangement that takes into account anticipated referrals will necessarily be greater than what would be paid by parties who are not in a position to refer business to each other. While the value agreed upon by parties who are in a position to refer business to each other and who take into account anticipated referrals will be a fair value *as between the parties*, such an arrangement is not “fair market value” under the Stark Act. Here, the compensation arrangement between the parties is greater than what would be paid in the absence of the ability of Dr. Saleh and Dr. Vaccaro to provide referrals for BRMC’s nuclear camera business.

In conclusion, we find that Relators have established that the aggregate compensation received by the doctors takes into account the volume or value of anticipated referrals generated

by the doctors for BRMC. 42 C.F.R. § 411.354(c)(2)(ii). We also find that BRMC had actual knowledge, or acted in reckless disregard or deliberate ignorance of, the fact that the aggregate compensation BRMC paid to the doctors “took into account” the volume or value of anticipated referrals. 42 C.F.R. § 411.354(c)(2)(iii). Accordingly, we find that Relators have established that an indirect compensation arrangement exists between the parties under the Stark Act.

ii. The 10% Collections Fee Arrangement

Relators also argue that an indirect compensation agreement exists for the time period in which V&S received 10% of all amounts collected on referrals to the GE machine while it remained located at V&S’s office because compensation to V&S from BRMC directly varied with the amount of referrals. Relators argue that this 10% fee directly varied with the number of referrals because as more referrals for tests on the GE camera were performed, more money was collected for the services, and thus the collections fee paid by BRMC to V&S increased in direct proportion to the number of referrals the doctors made.

Defendants argue that the 10% billing fee is permitted under the regulations as unit-based compensation deemed not to take into account the volume or value of referrals. (Defendant’ Joint Opposition, at 12, citing 42 C.F.R. §§ 411.354(d)(1) & (2).) However, payment based on a percentage of collections, as is the 10% billing fee, is not covered by the provisions of 42 C.F.R. § 411.354(d)(2). See 66 Fed.Reg. at 877-878. Accordingly, we find that the aggregate compensation received by the doctors based on the 10% billing fee varies with the volume or value of referrals generated by the doctors for BRMC, and BRMC was aware of the fact that the 10% fee it paid to the doctors varied with the amount of referrals. 42 C.F.R. § 411.354(c)(2)(ii) & (iii). Therefore, the 10% billing fee arrangement constitutes an indirect compensation arrangement between the parties for the period of time it was in existence.

2. Whether an Exception Applies

Once it has been determined that a financial relationship exists the burden shifts to defendants to establish the applicability of an exception. Kosenke, 554 F.3d at 95; Villafane, 543 F.Supp.2d at 687-688.

Defendants argue that their compensation arrangements qualify for protection under the Indirect Compensation Arrangement Exception, 42 C.F.R. § 411.357(p). Defendants also argue that their arrangements fit within the safe harbor provision of the Anti-Kickback Act for Personal Services and Management Contracts, 42 C.F.R. § 1001.952(d). In addition, Defendants argue that their arrangements are protected by the Equipment Rental Exception, 42 C.F.R. § 411.357(b) and the Space Rental Exception, 42 C.F.R. § 411.357(a); or fit within the corresponding safe harbor for Equipment Rentals, 42 C.F.R. § 1001.952(c) and Space Rentals 42 C.F.R. § 1001.952(b). The requirements for qualifying for an exception under the Stark Act and for fitting within the corresponding safe harbor provision under the Anti-Kickback Act are substantially similar and thus the same analysis would apply to both. Finally, Defendants argue that if the “Space and Services agreement” is deemed to be for a term of less than one year, it is nevertheless protected under the Fair Market Value Exception, 42 C.F.R. § 411.357(l). (Defendants’ Joint Opposition, at 16.) Because Defendants cannot satisfy all the requirements, we find that none of Defendants’ arrangements are protected by an exception or fit within a safe harbor.

a. Fair Market Value Requirement

All of the exceptions and safe harbors listed above require that compensation under the arrangement be fair market value and not determined in a manner that takes into account the volume or value of referrals. (*Indirect Compensation Arrangement*, 42 C.F.R. § 411.357(p)(1);

Equipment Rental, 42 U.S.C. § 1395nn(e)(1)(B)(iv), 42 C.F.R. § 411.357(b)(4), 42 C.F.R. § 1001.952(c)(5); *Space Rental*, 42 U.S.C. § 1395nn(e)(1)(A)(iv) &(v), 42 C.F.R. § 411.357(a)(4) & (5), 42 C.F.R. § 1001.952(b)(5); *Personal Services Safe Harbor*, 42 C.F.R. § 1001.952(d)(5); and *Fair Market Value Exception*, 42 C.F.R. § 411.357(l)(3).) As already discussed, the compensation received by the doctors from BRMC is not fair market value because it was determined in a manner that takes into account the volume or value of referrals, and therefore Defendants cannot satisfy this requirement of the exceptions and safe harbors.

b. “Set Out in Writing” Requirement

In addition, to satisfy the requirements of each of the exceptions and safe harbors the compensation arrangement must be set out in writing, signed by the parties, and specify the services, equipment, or premises covered by the agreement. (*Indirect Compensation Arrangement*, 42 C.F.R. § 411.357(p)(2); *Equipment Rental*, 42 U.S.C. § 1395nn(e)(1)(B)(i), 42 C.F.R. § 411.357(b)(1), 42 C.F.R. § 1001.952(c)(1) & (2); *Space Rental*, 42 U.S.C. § 1395nn(e)(1)(A)(i), 42 C.F.R. § 411.357(a)(1), 42 C.F.R. § 1001.952(b)(1) &(2); *Personal Services Safe Harbor*, 42 C.F.R. § 1001.952(d)(1) & (2); and *Fair Market Value Exception*, 42 C.F.R. § 411.357(l)(1).) Defendants run into several problems with their arrangements to satisfy this requirement.

First, Defendants argue that BRMC and V&S entered into a valid written “Spaces and Service Agreement.” Defendants allege that BRMC and V&S entered into a separate agreement for the temporary use of V&S’s office space where the GE Equipment was located, and the temporary use of the services of V&S for the time the GE Equipment was being leased by BRMC but was located at V&S’s offices. Defendants explain that the “Space and Services Agreement” came into effect October 1, 2003, by way of a “proposal” letter from V&S, along

with a V&S invoice. Defendants claim that BRMC agreed to the “proposal” when BRMC’s then Chief Financial Officer “approved and executed” the V&S invoice. (BRMC’s Concise Statement of Facts, at ¶ 19 ; V&S Defendants’ Concise Statement of Facts, at ¶ 21.)

The letter from V&S is dated October 2, 2003, and has a subject line stating: “Summary of charges for Nuclear Outpatient Testing.” (Letter from Drs. Vaccaro and Saleh to Leonhardt, Oct. 2, 2003.) The first sentence of the letter states: “This letter indicates the monthly charges for the nuclear facility while located at V&S Medical Associates.” (Id.) The monthly charges are indicated as follows:

Rent	\$2,500/month
Includes electric/cleaning/snow removal/garbage	
Billing	10% of total receipts
Laundry	
Telephone	
Internet Charges (cable)	\$24.00/month
Secretarial support	20 hrs per week @ \$10/hr

(Id.) The letter closes as follows:

The laundry and telephone charges would change monthly according to the charges from Verizon and Bradford Laundry. We would like to sell to the hospital the Archive system at a cost of \$2,000.00 and the hot lab at a cost of \$1,800.00. Please do not hesitate to contact is with any questions. The above monthly costs will be due on the 30th of each month.

(Id.)

Subsequently, V&S sent a “Statement” to BRMC dated October 2003, with the following charges:

Rent	\$2,500.00
Internet Charges	24.00
Secretarial Support	1000.00
Giamuso (Physicist)	440.00
Laundry	70.00
Telephone	Pending

Supplies per Test:

Cardolite tests costs	14 tests	288.68
Adenosine tests	18 tests	511.56
Hepatobilliary	1 test	11.40
Whole Body Bone	3 tests	34.20
Total		\$4,879.84

(V&S Statement for October 2003.) The letter further states:

(Above testing does not include medicine. That total will be taken from the receipts as the medicine is paid at costs by the insurer.)

(Id.)

The October 2003 Statement also includes handwritten initials and (presumably) the date the initials were placed on the Statement, which was sometime in November 2003. (Id.) The Statement also includes handwritten notes indicating the check number apparently used to pay the charges and a breakdown of the charges into what appears to be separate codes for BRMC's internal use. (Id.)

Defendants' arguments in support of their contention that a valid written agreement exists are weak and largely consist of the Defendants' conclusory statements. For example, BRMC states in its Brief in support of its motion for summary judgment that the "various arrangements are all set out in writing and signed by the parties, and specify what is covered by the arrangement." (BRMC's Memorandum in Support, at 12 (arguing that compensation arrangements meet the exception for indirect compensation arrangement).) BRMC uses similar language on the following page: "As noted above, the various arrangements are all set out in writing and signed by both parties." (Id. at 13 (arguing that the compensation arrangements fit within the equipment rental safe harbor).)

In regard to their position that a valid written Spaces and Services Agreement existed the Defendants also stated as follows:

The Relators next contend that there was no valid written agreement. In fact, there was. As pointed out in Paragraph 19 of BRMC's Concise Statement of Material Facts (Dkt. No. 115), the Space and Services Agreement was memorialized in the form of a written proposal and invoice from V&S, payment of which was authorized by the signature of BRMC's Chief Financial Officer. This was clearly a valid written agreement.

(Defendants' Joint Opposition, at 15-16.) Once again, Defendants do not argue to prove that the a valid written agreement exists, but instead contend that the agreement exists and support this statement by citing to their own statement of material fact that also states that the agreement exists.

Finally, in BRMC's Reply Brief the argument for the existence of a valid written agreement is as follows:

Relators next try to argue that the Spaces and Services Agreement was never signed by BRMC. BRMC's former Chief Financial Officer signed the invoice for the purpose of authorizing the terms proposed by V&S for the temporary arrangement while the GE Equipment was being used in the offices of V&S. See Leonhardt Affidavit, October 29, 2008, attached hereto as Exhibit 6. All Relators can counter with is a snide remark about a "mysterious initial" and then nitpick to whether certain minor charges such as \$70 laundry bill were reflected on the first invoice.

(BRMC Reply Brief, at 8.)

As is evident, Defendants do not seriously set forth an argument that the parties entered into a written agreement. Instead, Defendants rely on mere assertions that the written agreement existed. In addition, in its Concise Statement of Material Facts BRMC did not support their factual averment of a formal written agreement with citation to any record evidence. (See BRMC's Concise Statement of Material Fact, at ¶ 19.) The record evidence cited by the V&S Defendants in their Concise Statement only shows that V&S sent the October 2, 2003 letter, that V&S sent invoices to BRMC, and that on the October 2003 Statement (but on no other Statement) there are handwritten initials. (V&S Defendants' Concise Statement of material

Facts, at ¶ 21 n.36.) The V&S Defendants also cite to portions of Mr. Leonhardt's and Dr. Saleh's deposition testimony in support of proving the existence of the "Space and Services Agreement." (Id. at ¶ 21 n.35, 36, & 37.) However there is no testimony in these excerpts regarding the existence of a separate written space and services agreement, nor is there any testimony or questions in these excerpts regarding discussions or negotiations regarding such an agreement.

Defendants also did not cite to any record evidence to authenticate the initials on the October 2003 statement in their concise statements of material facts, or to affirm that the initials represent an approval of terms and execution of a separate agreement. It was not until BRMC's Reply Brief, that they offered an affidavit from Mr. Leonhardt indicating that the initials are those of Robert Fisher, the then-Senior Vice President and Chief Financial Officer at BRMC. (Affidavit of George Leonhardt, October 29, 2008, at ¶¶ 2 & 3.) Mr. Leonhardt also stated in this affidavit that "it was Mr. Fisher's practice to initial his signature to indicate (1) his approval for payment or (2) that he had read, noted and understood or approved the contents of a document." (Id. at ¶ 2.) Finally, Mr. Leonhardt states that Mr. Fisher's initials on the document "indicates . . . intent, on behalf of BRMC, to accept the terms proposed by V&S for the temporary arrangement that existed while the GE Camera was being used in V&S's office." (Id. at ¶ 3.) Notably, Defendants did not produce an affidavit or other evidence from Mr. Fisher himself, nor did they provide testimonial evidence from Dr. Saleh or Dr. Vaccaro that would support an allegation that the parties intended to and actually did enter into a formal written agreement.

The initial October 2, 2003 letter from V&S is a unilateral statement of monthly charges for a list of items. It is signed by V&S, but it is not signed by BRMC. We cannot view the

initials on the October 2003 statement as a BRMC signature to a written agreement titled the “Space and Services Agreement.” At best, the dated initials, along with a check number and breakdown of the bill, appear to indicate only that Mr. Fisher approved payment for the October 2003 Statement.

Moreover, an examination of the October 2, 2003 letter with the October 2003 Statement shows that there could not have been a meeting of the minds with respect to the terms of the so-called “Spaces and Services Agreement.” The letter indicates a charge of 10% of billings, but there is no corresponding charge for billings on the October Statement. In addition, the October Statement includes charges for a Physicist and for “Supplies per Tests” that were never mentioned in the October 2, 2003 letter. Thus, there could not have been a signed written agreement between the parties as to these potential terms of the agreement. Instead, it appears that the parties entered into an oral agreement with some precise terms, and some imprecise terms, that would last no more than month-to-month. We therefore conclude that there is no written “Space and Service Agreements” set out in writing and signed by the parties specifying the arrangements between the parties. Therefore Defendants cannot satisfy the written agreement requirements for the “Space and Services Agreement” to qualify for an exception or safe harbor.

Defendants have also failed to show that there is a written sublease between BRMC and V&S with regard to the Philips Camera. The only written contract between BRMC and V&S that specifies equipment is the Equipment Sublease, which specifies the GE Camera. Defendants contend that the October 1, 2003 Equipment Sublease is the written sublease agreement between BRMC & V&S regarding the Philips camera. Defendants rely on Section 5 of the Equipment

Sublease arguing that this section contemplated and provided for the effects of a “change or upgrade” of the equipment. Section 5 states as follows:

Section 5. Equipment Change or Upgrade

- (a) During the term of the GE Lease, [BRMC] will have the ability to change or upgrade the Equipment from GE or to change the equipment vendor should either the need or the opportunity for such a change occur, at [BRMC’s] discretion. Should [BRMC] make such an equipment or vendor change, such change will be done under two principles: (i) the change will not detrimentally affect [V&S] under this Sublease’s terms (i.e., no higher rental costs or fees, etc.), and (ii) [V&S] shall materially be in the same position as to the Equipment at the end of the Sublease as [V&S] now stands to the GE Equipment at the end of this Sublease.
- (b) As to (ii) above, presently [V&S] will own the GE Equipment at the end of the Sublease. The parties also understand and agree that it may not be in the interest of [BRMC] and/or [V&S] for changed Equipment (be it by a new vendor or a GE upgrade) to be leased to [V&S] for a new five-year term (i.e., the term of this Sublease). Instead, a shorter lease term or a different lease term (a further upgrading of Equipment with the then current vendor within the stated lease term occurs, with a potential, corresponding revised lease term) may be in the interest of [BRMC] and/or [V&S].

In accordance with this Section 5, [BRMC] and [V&S] have a good faith requirement to work through any issues and/or document provisions that require mutual understanding or cooperation with any such changed Equipment.
- (c) Should the change in vendor or equipment result in a lower cost of leasing the Equipment, this lower cost shall be passed through to [BRMC], and the parties shall amend Section 2 hereof to correspondingly reduce the rental hard costs described under Section 2(d)(i) and 2(d)(ii) hereof.

(Equipment Sublease, October 2, 2003.) Defendants argue that the Philips Camera is a change of equipment in accord with this section. However, there still is no written agreement reflecting a sublease of the Philips Camera between BRMC and V&S. “In this case, the only written contract in existence between the parties [regarding leasing a nuclear camera] is one that did not, and obviously was not intended to, apply to” an as-yet unknown nuclear camera. Kosenke, 554 F.3d at 96.

The Equipment Sublease concerned only one camera, the GE Camera, and Section 5 itself contemplates that a change or upgrade of the GE Camera would raise new issues that must be accounted for at a later date, presumably in a written agreement since the unknown issues could not be negotiated until BRMC upgraded or changed the equipment. At best, Section 5 permits an upgrade or change in equipment under certain general guiding principles. Section 5 does not act as a provision permitting the mere substitution of equipment and leaving all other terms of the agreement in place, and having the Equipment Sublease now be read as a sublease for the new camera. The Equipment Sublease entered into in October 2003 could not account for the relevant arrangement at the time when the Philips camera was acquired. Kosenke, 554 F.3d at 96-97.

Even though there was no Philips Camera sublease, BRMC made monthly rental payments on the Philips Camera to V&S in the amount of \$4,494.77 and monthly service agreement payments of \$2,299.14. There is no term to account for the monthly payments in the Equipment Sublease. In addition, even after the Philips camera was acquired, BRMC continued to make payments to V&S under that agreement for the GE Equipment that was no longer being used. Thus we fail to see how the Equipment Sublease can be construed as a written agreement when substantial payments on new equipment are not accounted for while the payments for the old equipment continue under the terms of the Equipment Sublease.

Significantly, once the Philips Camera was acquired, absent a new contract or an amendment to the Equipment Sublease, there simply is no written agreement between BRMC and V&S that “specifies the [Philips’s] equipment” as required by the equipment rental exception and safe harbor. 42 C.F.R § 411.357(b)(1); 42 C.F.R. §1001.952(c)(1) & (2). The only agreement regarding the Philips camera is between Philips and V&S. BRMC did execute a

guaranty in favor of Philip's on the Philip's camera, but this guaranty is not a sublease for equipment and contains no terms that could be interpreted as a sublease. We also note that there was no written agreement obligating BRMC to reimburse V&S for the GE buyout, nor was there a written agreement permitting V&S to possess the GE camera even after BRMC had essentially purchased the camera.

For the above reasons Defendants cannot satisfy an exception or qualify for a safe harbor.

3. Submission of Claims by BRMC

Having found a financial relationship and that no exception applies, we next examine whether BRMC submitted claims for payment to Medicare for designated health services based on referrals from Drs. Vaccaro and Saleh.

The Stark regulations define "referral" in relevant part as follows:

Referral--

(1) Means either of the following:

- (i) . . . the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B,
- (ii) . . . a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service,

42 C.F.R. § 411.351. Relators have submitted spreadsheets produced by CMS listing inpatient and outpatient claims submitted by BRMC to Highmark Medical Services for claims on which either Dr. Vaccaro or Dr. Saleh are identified as the attending, referring, or other physician.

BRMC admitted in its discovery responses that each line item properly identified an inpatient or

outpatient claim submitted by BRMC to Medicare. We therefore find that BRMC has submitted claims for designated health services based on referrals from Dr. Vaccaro and Dr. Saleh.

In response, BRMC asserts that it is not possible to determine if the referrals made by the doctors and listed in the CMS spreadsheets are prohibited referrals without referencing each underlying medical record to examine the services rendered to the patients covered by the claims forms. (Defendants' Joint Opposition, at 16.) We disagree. BRMC admitted in discovery that BRMC submitted claims based on referrals from Dr. Vaccaro and Dr. Saleh as identified in the spreadsheets provided by CMS. BRMC is apparently now arguing that some of the referrals identified by CMS may be based on BRMC's misidentification of the physician when BRMC submitted the claims to CMS. BRMC has not provided a single example to show that such misidentification by BRMC occurred. In any event, the time for BRMC to challenge those items was in discovery.

4. Violation of the Stark Act

We find that the doctors have a financial relationship with BRMC as set forth above, that the doctors have made referrals to BRMC, and that BRMC has submitted claims pursuant to such referrals. Thus, we conclude that Defendants have violated the Stark Act. 42 U.S.C. § 1395nn(a)(1). As discussed below, however, we are unable to conclude at this stage that Defendants' violation of the Stark Act was done knowingly for purposes of the False Claims Act.

Based on the large amount of claims involved and the potential complexity of determining damages, we will defer ruling on damages until after the parties have had an opportunity to address these issues. A separate briefing schedule to address the damages issues will be issued at a later date.

B. The Anti-Kickback Act

Section 1320a-7b of the Anti-Kickback Act provides for criminal penalties for certain acts involving Federal health care programs. Relevant to the present case, the Act makes it unlawful to knowingly and willfully solicit or receive any remuneration for referrals of services covered by a Federal health care program, and unlawful to knowingly and willfully offer or pay any remuneration for referrals of services covered by a Federal health care program. 42 U.S.C. § 1320a-7b(b). In determining whether a violation of the Anti-Kickback Act occurred we focus on whether the payments made by BRMC were knowingly intended to induce or reward referrals from Dr. Saleh and Dr. Vaccaro.

Relators argue that the record evidence establishes that one of the purposes of the payments by BRMC was to induce or reward referrals from the doctors. United States v. Greber, 760 F.2d 68, 72 (3d Cir. 1985). Relators primarily rely on the evidence set forth above showing that BRMC entered into the sublease and other arrangements because BRMC expected that in exchange for payments to V&S, BRMC would receive Dr. Vaccaro and Dr. Saleh's referrals of patients for nuclear camera work.

While we have found that the record evidence establishes that Defendants "took into account" the value or volume of referrals for purposes of the Stark Act, we are unable to conclude as a matter of law that Defendants "knowingly and willfully" paid and received remuneration under the sublease and other arrangements for referrals of services. The manner in which Defendants valued the non-compete payments, in our view, was roughly the number of V&S patients that used the machine. Thus, we found that the Stark act was violated because the arrangement "took into account" anticipated referrals. However, much of the evidence in

support of establishing the requisite intent of Defendants implicates credibility decisions that are the province of the fact-finder at trial.

The evidence put forth by Defendants shows that BRMC and Dr. Vaccaro and Dr. Saleh were in a struggle to resolve a serious, longstanding dispute. On the one hand, BRMC had lost, and stood to continue to lose, a significant amount of referral business from V&S as a result of V&S obtaining its own nuclear camera. On the other hand, Dr. Vaccaro and Dr. Saleh were concerned that they would lose their hospital privileges and other benefits if BRMC enforced its Policy against them.

BRMC wanted V&S out of the nuclear camera business because of the detrimental impact it had on BRMC and thus sought a resolution that would get V&S out of the business. V&S realized that BRMC wanted V&S out of the nuclear camera business but did not want to give up the potential future revenue that would come from operating their own nuclear camera. Therefore, V&S essentially sought compensation from BRMC for the business it would lose by leasing the GE Camera to BRMC and agreeing to not compete with BRMC's nuclear camera business. Accordingly, during negotiations V&S valued its lost economic opportunity of no longer having their own nuclear camera by considering its past performance and expected future performance. Naturally, that is the compensation they sought from BRMC. BRMC, in turn, knew that V&S was making money off of its own nuclear camera and would not simply agree to give up its potential future business without compensation. BRMC eventually proposed an amount of compensation lower than that proposed by V&S and the parties came to an agreement.

A fact-finder viewing this evidence could conclude that Dr. Vaccaro and Dr. Saleh did not knowingly and willfully solicit or receive remuneration from BRMC for referrals, and that BRMC did not knowingly and willfully offer or pay remuneration to the doctors for referrals.

The Anti-Kickback Act requires proof of intent, whereas the Stark Act prohibits Defendants from taking into account referrals regardless of the intent of the parties.

Defendants rely heavily on the fact that they have never explicitly required that the doctors refer patients to BRMC. A fact-finder could decide that Defendants valued the non-compete payments at a fair market price that did account for the amount of business V&S could generate, but that the parties did not knowingly and willfully make and receive payments in order to induce or gain such referrals. The fact that Dr. Vaccaro and Dr. Saleh were not required to refer any patients to BRMC may lead a fact-finder to believe that the requisite intent of Defendants is lacking. In addition, a fact-finder may consider what recourse BRMC would have had if Dr. Vaccaro and Dr. Saleh did not refer patients to BRMC.

In light of the record evidence, Defendants will have a difficult challenge to prove to the fact-finder that they did not have the requisite intent. A fact-finder will take into consideration not only the statements by Defendants and their counsel during negotiations, the assessments of the arrangement that show that the value of the non-compete is roughly equal to the amount of business V&S could generate for BRMC, but also the fact that after the arrangement was entered into the doctors did refer their patients to BRMC. Complicating the factual issue is the rural nature of the Bradford area which limits the number of facilities available for referrals from the doctors. Thus, even though the doctors were not required to refer to BRMC, the fact-finder must consider whether, as a practical matter, the doctors had any real choice as to where they made referrals and whether that fact has any impact on the question of the parties' intent.

In addition, Relators claim that Dr. Vaccaro and Dr. Saleh could have refused to enter into an arrangement with BRMC and continued to generate revenue with their own nuclear camera thereby avoiding any violation of federal law. Similarly, Relators argue that BRMC's

threat to enforce its Policy and revoke the doctors' privileges was never serious as shown by BRMC's failure to enforce it during years of negotiations. In addition, Relators discount BRMC's claim that it wanted to fulfill its mission by hiring a full-time cardiologist at BRMC. We conclude that these and other issues are for a fact-finder at trial. Viewed in a light most favorable to Defendants, we find that genuine issues of material fact exist that preclude us from finding that Defendants violated the Anti-Kickback Act.

C. The False Claims Act

Section 3729 of the False Claims Act imposes liability, in relevant part, on any person who:

- (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

31 U.S.C. § 3729(a)(1)-(2). The focus of our inquiry is on whether Defendants acted “knowingly” for purposes of the False Claims Act. The false Claims Act defines “knowing” and “knowingly” as follows:

(b) Definitions.--For purposes of this section--

(1) the terms “knowing” and “knowingly” --

(A) mean that a person, with respect to information--

- (i)** has actual knowledge of the information;
- (ii)** acts in deliberate ignorance of the truth or falsity of the information; or
- (iii)** acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

31 U.S.C. § 3729(b). Thus, liability is imposed not only for a person with actual knowledge of a false or fraudulent claim and the intent to defraud, but also imposes liability for a person who acts in deliberate ignorance or reckless disregard of a false or fraudulent claim and who does not intend to defraud.

Relators argue that Defendants acted knowingly within the meaning of the False Claims Act. In support of their argument, Relators argue that the record evidence shows that Defendants and their attorneys were aware from the beginning of their discussions that led to the sublease and other arrangements that their conduct raised issues under the Stark Act and the Anti-Kickback Act. See Raspanti Letter, 1/22/2002, at 1 (BRMC's Policy "violate federal law, in particular, the federal anti-kickback criminal statute", citing Kabala Letter, 12/4/01); Raspanti Letter, 1/22/2002, at 2 (noting that Stark Statute and the False Claims Act provide civil penalties "for those who enter into arrangements which compensate based upon referrals"); id. (asserting that BRMC "is conditioning privileges on referrals streams. This is precisely the type of arrangement that the anti-kickback laws were intended to prevent"); Raspanti Letter, 2/15/2002, at 1 ("the anti-kickback laws are violated even where only 'one purpose' of a payment or exchange is to induce referrals"); id. at 5 ("We know of no case that more clearly establishes a hospital's attempt to extract an exclusive referral stream from a physician"); Leonhardt Letters, 6/26/2002 and 7/30/2001 (stressing the need to structure the venture in such a way that it satisfied the Stark statute); Raspanti Letter, 1/17/2003, at 3 (asking for "[a]ll opinions concerning the legality of the nuclear camera venture" contemplated between BRMC and physicians on the hospital medical staff; id. at 3 n.4 ("I am sure that we can all agree that neither party wishes to become involved in a business venture which is in violation of federal or state law"); and Kabala letter, 2/5/2003, at 4; BRMC 30(b)(6) Dep. at 138; Saleh Dep. at 101 (parties considered it

essential to obtain advisory opinion from the Office of the Inspector General regarding the legality of the venture before entering into any “under arrangements” joint venture).

This evidence shows that Defendants and their attorneys, while engaged in ongoing lengthy negotiations, were aware that the potential arrangements they were contemplating entering into implicated the Stark Act and the Anti-Kickback Act. Again, however, viewed in a light most favorable to Defendants, we find that genuine issues of material fact exist that preclude us from finding that Defendants acted “knowingly” for purposes of the False Claims Act.

Based on the evidence a fact-finder could believe that when the parties entered into the preliminary sublease and the Equipment Sublease, it was apparent, or should have been apparent, to Defendants that BRMC wanted to lease the GE Camera in order to obtain Dr. Saleh’s and Dr. Vaccaro’s referrals it had lost when V&S obtained the GE Camera. On the other hand, a fact-finder could also believe that Defendants could not have acted “knowingly” based on the fact that they carefully sought to avoid requiring referrals and attempted to make a business decision based on the fair market value assessment of the arrangements.

Again, the record evidence is not strongly in favor of Defendants as it tends to show that Defendants entered into the Equipment Sublease fully aware that the arrangement, which had at its core a non-compete payment roughly equal to the referral business BRMC would gain from the doctors and the business V&S would lose from abandoning its own camera, may not be permitted under the Stark Act and Anti-Kickback Act. However, we are unable to conclude as a matter of law that Defendants acted “knowingly” for purposes of the False Claims Act.

IV. Conclusion

For the foregoing reasons, we will deny Defendants' motions for summary judgment, and grant in part, and deny in part, Relators' motion for summary judgment.

An appropriate Order follows.

November 10, 2010
Date

Maurice B. Cohill, Jr.
Maurice B. Cohill, Jr.,
Senior District Judge